

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF ARIZONA
3

4
5 In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
6 Products Liability Litigation)
7) Phoenix, Arizona
8) May 16, 2018
9 Doris Jones, an individual,) 1:00 p.m.
10)
11 Plaintiff,)
12) CV 16-00782-PHX-DGC
13 vs.)
14)
15 C.R. Bard, Inc., a New)
16 Jersey corporation; and Bard)
17 Peripheral Vascular, Inc., an)
18 Arizona corporation,)
19)
20 Defendants.)
21)
22)
23)
24)
25)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(Jury Trial - Day 2 - P.M. Session)
(Pages 345 through 468, inclusive.)

Official Court Reporter:
Laurie A. Adams, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Suite 312
401 West Washington Street, Spc 43
Phoenix, Arizona 85003-2151
(602) 322-7256

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

1 APPEARANCES:

2 For the Plaintiff:

3 GALLAGHER & KENNEDY PA

4 By: Mark S. O'Connor, Esq., Esq.

5 By: Paul L. Stoller, Esq.

6 By: Shannon L. Clark, Esq.

7 By: C. Lincoln Combs, Esq.

8 2575 East Camelback Road, Suite 1100

9 Phoenix, Arizona 85016

10 LOPEZ MCHUGH LLP

11 BY: Ramon Rossi Lopez, Esq.

12 100 Bayview Circle, Suite 5600

13 Newport Beach, California 92660

14 HEAVISIDE REED ZAIC

15 By: Julia Reed-Zaic, Esq.

16 By: Laura Elizabeth Smith, Esq.

17 312 Broadway, Suite 203

18 Laguna Beach, California 92651

19 For the Defendants:

20 NELSON MULLINS RILEY & SCARBOROUGH LLP

21 By: Richard B. North, Jr., Esq.

22 By: Elizabeth C. Helm, Esq.

23 By: James F. Rogers, Esq.

24 By: Matthew B. Lerner, Esq.

25 201 17th Street NW, Suite 1700

Atlanta, Georgia 30363

I N D E X

20 WITNESS:DIRECTCROSSREDIRECTRECROSS

21 ROBERT MCMEEKING, Ph.D.

22 By Mr. Stoller

347

447

23 By Mr. North

427

INDEX OF EXHIBITS24 EXHIBITIDENTRECEIVED

25 876

BPV-17-01-00009381 -398,
Pages 30-44 of Notebook No. 7013,
Project: Recovery Filter Arm
Fatigue Testing, Chanduszko
Deposition, 04/23/2015

420

420

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

P R O C E E D I N G S

THE COURT: Your next witness, counsel.

MR. STOLLER: Your Honor, plaintiffs call Robert McMeeking.

(The witness was sworn.)

01:00PM

THE COURTROOM DEPUTY: Could you state your name and spell it for the record?

THE WITNESS: Robert McMeeking, M-C-M-E-E-K-I-N-G.

THE COURTROOM DEPUTY: Thank you, sir. Please come have a seat.

01:00PM

MR. STOLLER: Your Honor, may I introduce myself to the jury? They probably don't remember me from the back of the courtroom.

THE COURT: You may.

MR. STOLLER: Good afternoon, Ladies and Gentlemen. My name is Paul Stoller. I represent Doris Jones.

01:01PM

All set, Doctor?

THE WITNESS: I have got some stuff in my bag but I can get it out later. Thank you.

ROBERT MCMECKING, Ph.D.,
called as a witness herein, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. STOLLER:

Q. Would you introduce yourself to the jury?

01:01PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. My name is Robert McMeeking. I'm from Santa Barbara,
2 California.

3 Q. And you have the title Doctor, but you are not a medical
4 doctor, correct?

5 A. No. I'm a Doctor of Philosophy in Engineering.

01:01PM

6 Q. So you are an engineering doctor?

7 A. Correct.

8 Q. What do you do for a living, Dr. McMeeking?

9 A. I'm a Professor of Mechanical Engineering at the University
10 of California, Santa Barbara.

11 Q. What is mechanical engineering?

12 A. Mechanical engineering is the creation, the design, and the
13 analysis of mechanical devices.

14 Q. Does that include medical devices?

15 A. Yes, it does.

01:01PM

16 Q. We'll talk a bit about your background and qualifications.
17 But would you tell the jury why you are here today?

18 A. I'm here to testify about Bard's design and testing of its
19 IVC filters, particularly the Recovery, the G2, and the Eclipse
20 Filter, and to discuss the problems I found with the design of
21 those filters and to tell you about the impact that the
22 defective design of the filter had on the filter that is in
23 Mrs. Jones.

01:02PM

24 Q. Have you prepared a summary of your opinions to help
25 illustrate your opinion to the jury?

01:02PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. I have.

2 MR. STOLLER: Gay, would you please pull up
3 Demonstrative Exhibit 4557.

4 Thank you.

5 BY MR. STOLLER:

6 Q. Doctor, is this that demonstrative exhibit?

7 A. It is, yes.

8 MR. STOLLER: Your Honor, may I publish this to the
9 jury?

10 THE COURT: Any objection?

01:02PM

11 MR. NORTH: I'm going to object. I think the witness
12 needs to testify first as to his opinions.

13 THE COURT: I'm going to sustain the objection. I
14 think it's leading until he's actually gone through those
15 points.

01:03PM

16 MR. STOLLER: Let's take it down for a moment and
17 then we'll come back.

18 BY MR. STOLLER:

19 Q. Doctor, would you tell the jury in summary what your
20 opinions are in this case?

01:03PM

21 A. Yes. My opinion is that the Eclipse Filter is defectively
22 designed, and that it was inadequately tested. And the testing
23 that was carried out had deficiencies in it, and some tests
24 were omitted altogether. And that the company did not identify
25 the root cause of failures that were occurring in the first

01:03PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 version of the filter, the Recovery. And as a consequence,
2 they were not -- they were not completely sure of what was
3 causing those failures, and therefore, they were not able to do
4 a redesign of the filter to adequately address the reduction of
5 the incidence of those failures or to be able to eliminate them
6 completely or to reduce them to the greatest extent feasible.

01:04PM

7 Q. Do you have any opinions with respect to the effect of
8 those designs and testing failures on the filter that Mrs.
9 Jones had?

10 A. Yes. It is my opinion that those defects in the design
11 caused the problems that Mrs. Jones suffered from her filter.

01:04PM

12 Q. Let's talk a bit about your background. You are a
13 Professor of Mechanical Engineering and Material Science at
14 UCSB, correct?

15 A. That's correct, yes.

01:04PM

16 Q. How long have you taught mechanical engineering and
17 material science?

18 A. I have taught at University level for 45 years, over 45
19 years. Sorry.

20 Q. Excuse me.

01:04PM

21 In addition to UCSB, where else have you taught?

22 A. As a graduate assistant I taught at Brown University and
23 then I was at Stanford University for two years, 1976 to 1978.
24 Then I moved to the University of Illinois at Urbana-Champaign
25 and I was there from 1978 to 1985, at which stage I moved to

01:05PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Santa Barbara.

2 In addition, I have a part-time appointment at the
3 University of Aberdeen in Scotland. I have had that
4 appointment since about 2009.

5 Q. I was going to ask you, you have a little bit different
6 accent than I do. Where are you from?

01:05PM

7 A. I was born in Glasgow in Scotland.

8 Q. When did you move to the United States?

9 A. I moved to United States in 1972 to do my graduate degrees.

10 Q. What were your graduate degrees in?

01:05PM

11 A. I have a Master of Science and Doctor of Philosophy both in
12 engineering.

13 Q. Now you teach engineers?

14 A. I do, yes.

15 Q. What courses -- do you teach both graduate and
16 undergraduate students?

01:05PM

17 A. I do, yes.

18 Q. And so you are a doctor and you teach people who are
19 becoming doctors of engineering?

20 A. Yes, I do.

01:06PM

21 Q. What subjects do you teach?

22 A. I teach stress analysis; I teach finite element computer
23 methods of analysis; I teach topics to do with the stability of
24 structures. I teach behavior of materials; I teach strength of
25 materials; I teach fracture of materials; I teach fatigue of

01:06PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 materials; and I teach design of components and devices. And
2 these are all issues which are relevant to the trial today.

3 Q. Are you a member of any professional organizations or
4 honorary societies?

5 A. Yes. I'm a member of the National Academy of Engineering. 01:06PM

6 It's a body that elects its members, and you are elected for
7 the significance and impact and high quality of your

8 engineering accomplishments. There are 2,500 members of the

9 National Academy of Engineering out of approximately 1.5

10 million engineers who are employed in the United States. 01:07PM

11 Q. So it's a pretty prestigious organization?

12 A. Yes, it is.

13 Q. Pretty selective?

14 A. Yes.

15 Q. Hard to get into? 01:07PM

16 A. Yes. I'm very pleased to be a member.

17 MR. NORTH: Objection.

18 THE COURT: Sustained on leading.

19 MR. STOLLER: Fair enough.

20 BY MR. STOLLER: 01:07PM

21 Q. Are you a member of any other professional organizations or
22 societies?

23 A. Yes. I'm a fellow of the Royal Academy of Engineering in
24 the UK; I'm a fellow of the Royal Society of Edinburgh also in

25 the UK; and I'm a life member of the American Society -- life 01:07PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 fellow of the American Society of Mechanical Engineers.

2 Q. What does it take to become a member of those organizations
3 or a fellow of those organizations?

4 A. Again, it's a matter of the significance and high quality
5 of your contributions in engineering and associated subjects.

01:07PM

6 And in the case of American Society of Mechanical Engineers
7 it's a matter of being both a significant contributor and
8 senior member of the organization.

9 Q. You have received something called the Timoshenko Medal of
10 the American Society of Medical Engineers. Would you tell the
11 jury what is?

01:08PM

12 A. Oh, it's the Timoshenko Medal of the American Society of
13 Mechanical Engineers, and that is the highest medal or award or
14 prize which is given by the American Society of Mechanical
15 Engineers to individuals like myself who work in the area of
16 stress analysis and solid mechanics.

01:08PM

17 Q. Have you written any articles regarding medical -- I'm
18 sorry -- mechanical engineering?

19 A. Yes. I have written over 250 peer-reviewed articles in the
20 area of mechanical engineering that I work in.

01:08PM

21 Q. What is a peer-reviewed article?

22 A. A peer-reviewed article is an article that has been
23 submitted to a technical journal, and then it has been
24 reviewed. It's been read and assessed by individuals who are
25 experts in the relevant area. And they make a recommendation

01:09PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 about whether the paper is good enough and correct enough and
2 significant enough to be published in the technical journal.

3 Q. And if it doesn't pass the review of those peers, what
4 happens to your article?

5 A. The article is rejected, and it doesn't get published. 01:09PM

6 Q. Do any of the articles of those 250 articles you have
7 published in the peer-reviewed journals, do they have anything
8 to do with the issues you address in this case?

9 A. Yes, they do.

10 Q. What? 01:09PM

11 A. They address topics to do with stress analysis, finite
12 element method of computer analysis, stability of structures,
13 strength of materials, fatigue of materials, fracture of
14 materials. I have also published papers on the adhesion of
15 cells and tissue to other surfaces and materials. And I have 01:09PM
16 published papers on the remodeling of tissues and biological
17 cells in living things.

18 And also I have published a couple of papers on
19 medical implants, namely prosthetic heart valves.

20 Q. In addition to writing articles for peer-reviewed journals, 01:10PM
21 have you played any other roles with respect to the journals
22 for your profession?

23 A. Yes. I was the editor-in-chief of the American Society of
24 Mechanical Engineers Journal of Applied Mechanics, which is
25 their flagship journal, actually, and it's also the journal 01:10PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 that is most important in the area of stress analysis and solid
2 mechanics. I was the editor-in-chief for 10 years and,
3 therefore, I supervised the peer review process for selecting
4 and rejecting, which we did most -- we rejected more papers
5 than we accepted to be published in the journal.

01:10PM

6 Q. Other than teaching mechanical engineers and writing
7 papers, do you practice mechanical engineering?

8 A. Yes. I do that in the form of consulting for companies.

9 Q. And what kind of consulting do you do?

10 A. I do -- the consulting that I do is for a variety of
11 companies including medical implant companies. And the sort of
12 thing that I do is to review the design of the devices that
13 they are producing or contemplating producing, look at the
14 possible ways that those devices can fail, and review the
15 testing and analysis of those devices to make sure that the
16 companies are doing the appropriate things to ensure the safety
17 and reliability and effectiveness of those devices.

01:11PM

01:11PM

18 And I also make recommendations to them on the sort of
19 bench testing or laboratory testing that they should carry out
20 to address the issues that I just discussed. And some of the
21 work that I do involves doing analysis in calculations for the
22 companies, and in other cases it's a matter of reviewing the
23 kind of calculations and analysis that the companies have done.

01:12PM

24 Q. For about how many medical device companies have you served
25 as a consultant?

01:12PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. About 15.

2 Q. Over how many years?

3 A. That's over about 30 years.

4 Q. What kind of devices have you consulted with those
5 companies about?

01:12PM

6 A. I have consulted with companies on prosthetic heart valves,
7 stents, and breast implants.

8 Q. You just described a bit about the process that you
9 undertake when you consult with those companies. Is that
10 similar to what you have done in this case?

01:12PM

11 A. Yes. I approached the work in this case in the same way I
12 would when I'm carrying out consulting work, especially for
13 medical device implant companies.

14 Q. And you are testifying here today as an expert witness on
15 our behalf. Have you worked as an expert witness in other
16 cases?

01:13PM

17 A. Yes, I have.

18 Q. How often?

19 A. How often? I have worked in the Bard cases; I have worked
20 in other litigation concerning Cook IVC Filters and quite
21 sometime ago, about 25 years ago, I worked on a couple of cases
22 concerning a bicycle accident and the failure of a knee
23 prosthesis.

01:13PM

24 Q. Is expert work for litigation a large amount, I don't know,
25 say 40 percent or more of what you do?

01:13PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. No. It's less than that.

2 Q. How much of your work or income comes from being expert
3 work in these kind of cases?

4 A. On average, less than 15 percent over the last 8 to 10
5 years.

01:13PM

6 Q. You have, in fact, provided expert testimony in another IVC
7 filter case, is that correct?

8 A. That's correct.

9 Q. And that's the Cook case I mentioned?

10 A. Yes that's the Cook case, yes.

01:13PM

11 Q. Did you find a problem with the design of the filter in
12 that case?

13 A. Yes, I did.

14 Q. Are those findings related to what you did here?

15 A. No. They are not related because the filters are
16 different.

01:14PM

17 Q. You are being paid by us to be here today?

18 A. I am.

19 Q. What do you charge us?

20 A. I charge \$400 an hour for regular consulting, and when I'm
21 testifying, or I'm being deposed, like today, I'm testifying
22 today, I charge \$800 an hour.

01:14PM

23 Q. Is that the same rate you charge in all your consulting
24 work?

25 A. Well, since the other consulting work other than litigation

01:14PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 cases doesn't involve testimony, I charge \$400 an hour to the
2 companies that I carry out consulting work for.

3 Q. Let's talk about a little bit about mechanical engineers
4 and how they do their work.

5 Are there principles that engineers generally follow
6 in applying to the design and testing of medical devices?

01:14PM

7 A. Yes. There's a variety of principles that they pursue.

8 One of the ones that's paramount is patient safety. They need
9 to, they should, they must, investigate thoroughly the

10 conditions that the device will operate within when it's

01:15PM

11 implanted in the human body. They should understand the

12 function and purpose of the device. And they should identify

13 the ways that the device can fail and how it can be compromised
14 while it's implanted within the human body.

15 Having identified the ways in which the filter --

01:15PM

16 sorry -- the device can fail, they should then carry out what's

17 called worst-case assessments, worst-case testing of the device

18 to make an assessment of the consequences of the worst

19 conditions the device can experience after it's been implanted.

20 Q. And once they have done that, what must they do?

01:15PM

21 A. Sorry. Can you repeat the question?

22 Q. Once you have followed those rules, is there anything else
23 that engineers must do?

24 A. They must iterate the design and try and reduce the failure

25 modes to the greatest extent possible in conjunction with the

01:16PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 objectives of the device, whatever that might be.

2 MR. STOLLER: Would you pull up Exhibit 4558 for me,
3 please.

4 BY MR. STOLLER:

5 Q. And Doctor, hopefully in front of you is Exhibit 4558. Is
6 this a demonstrative exhibit that you prepared to assist you in
7 illustrating your testimony to the jury?

01:16PM

8 A. Yes, it is.

9 MR. STOLLER: Your Honor, may we show 4558 to the
10 jury?

01:16PM

11 MR. NORTH: Your Honor, same objection. And leading.

12 MR. STOLLER: He just testified --

13 THE COURT: Overruled. He's covered this. You may
14 display it.

15 MR. STOLLER: Thank you.

01:17PM

16 BY MR. STOLLER:

17 Q. Dr. McMeeking, are these the rules you just testified to
18 the jury?

19 A. Yes, they are. Yes.

20 Q. And you have titled this slide, "Standards of Safe and
21 Reliable Design," correct?

01:17PM

22 A. Correct.

23 Q. What are the sources of these rules?

24 A. The sources -- are there's a variety of them. And
25 generally speaking, organizations like the American Society of

01:17PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Mechanical Engineers provide guidance and guidelines that these
2 are the appropriate methods to use in reliable and safe design.
3 In addition, somewhat more specialized organizations such as
4 the International Medical Device Regulators Forum has provided
5 guidance on these kind of issues as well. And there are
6 several textbooks, and specifically I would mention Dieter and
7 Schmidt, which is a textbook for educating students on the
8 design of devices and components. And it provides these kind
9 of guidelines as to the appropriate way for engineers to carry
10 out safe and reliable design.

01:17PM

01:18PM

11 Q. You have identified under the "Must Test For Those Problems
12 and Failure Modes" a couple of subrules, I guess I will call
13 them, or indents and you discussed those a bit. But could you
14 please explain to the jury what those mean?

15 A. Well, the statements that are made are must replicate the
16 situation of the device as closely as possible. In other
17 words, you must look at the environment which the device will
18 experience once it's implanted in the human body, and you must
19 try to duplicate that condition when you carry out the tests in
20 the laboratory that you are planning to undertake to bring the
21 device into the conditions that it will experience after it has
22 been implanted.

01:18PM

01:18PM

23 And then the other statement is that you must test for
24 the worst-case scenario. The worst-case scenario is something
25 you need to identify in the course of the work that you do

01:19PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 looking at the way that the filter -- sorry -- the medical
2 device will experience conditions in the human body and having
3 identified and made an assessment of the worst-case conditions
4 then those are the conditions that you should implement in the
5 testing of the device.

01:19PM

6 Q. Is that a principle that is espoused by the organizations
7 that you identified earlier in the textbook?

8 A. Yes, it is. And it's fundamental to safe and reliable
9 design and engineering.

10 Q. Why must you test for worst-case scenario?

01:19PM

11 A. You must test for worst-case scenario so that you
12 understand fully the consequences of the conditions that might
13 occur to the device once it is implanted in the human body.
14 And having understood the consequences of those worst-case
15 conditions, you can then make appropriate decisions about
16 redesign of the device or other steps that you might take to
17 make sure that the device is safe and reliable after it has
18 been implanted.

01:20PM

19 Q. Kind of like building a car to withstand a car crash?

20 A. Yes. That's right. I mean, if you are building and
21 designing a car, you need to worry about front end collisions,
22 rear end collisions, the car rolling over, other bad things
23 that can happen. And you should think about the safety
24 features that you can implement in the vehicle whether it's the
25 way that you design the body and the structure or whether it's

01:20PM

01:20PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 the features and things you put in the vehicle such as safety
2 belts and air bags.

3 Q. Doctor, let's talk a little bit more specific about the
4 things you did in this case.

5 What materials did you look at or review in coming to
6 your opinions in this case?

01:21PM

7 A. I reviewed documents from Bard concerning the design and
8 the testing of the IVC filters; I looked at reports that were
9 produced by experts on both sides of the litigation and
10 reviewed those reports; I also read deposition testimony which
11 was given by employees of Bard in the cases where these
12 employees were involved in design and testing of the filters.

01:21PM

13 Q. In looking at testing documents and materials from Bard,
14 did you focus on specific kinds of tests?

15 A. Yes. I focused on finite element analysis documents, and I
16 focused on documents concerned with bench testing, as it's
17 called, laboratory testing of the behavior of the filter in
18 terms of its resistance to fracture, its resistance to tilting,
19 and its resistance to things like perforation and movement
20 within the IVC.

01:21PM

01:22PM

21 Q. You used the term "finite element analysis." Would you
22 explain to the jury what that is?

23 A. Yes. Finite element analysis is a computer method of doing
24 calculations. These are calculations that you can do on a
25 piece of paper, but by doing them in the computer, when these

01:22PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 calculations become complex, it is often quicker and more
2 efficient and more effective to do them by computer. And when
3 they are done in the correct way, these calculations are also
4 quite accurate and they can be used to crosscheck against other
5 ways of doing the calculations such as where you carry out
6 calculations on a piece of paper, just as the calculations you
7 do on a piece of paper can be crosschecked with the results of
8 the finite element calculations.

01:23PM

9 Q. So it's a computer program?

10 A. It's a computer program, yes.

01:23PM

11 Q. Let me step back for a minute. As a mechanical engineer,
12 when you are making your determinations about how materials
13 like IVC filters are going to react in certain situations, are
14 you performing mathematical calculations? How are you
15 determining this?

01:23PM

16 A. Yes. These are mathematical calculations that implement
17 principles of physics, mainly, to predict how the device will
18 respond to the environment that it finds itself in and to look
19 at how it will move and how it will experience what are called
20 stresses and strains as a consequence of the condition that the
21 device is operating within.

01:23PM

22 Q. And I think you said that you can use those finite element
23 analysis, do you sometimes call them FEA?

24 A. They are often called FEA.

25 Q. So if I say "FEA" you will know what I'm saying?

01:24PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. I will know what you mean, yes.

2 Q. Hopefully the jury will follow us.

3 You said when you use the FEA sometimes you use it to
4 check your math. Did I understand that correctly?

5 A. You use it in various ways. You use it to make predictions
6 by itself, but one always wants to have a crosscheck to make
7 sure that things are being done reliably and accurately. So
8 checking the mathematical calculations you do on a piece of
9 paper is one way that FEA can be used in this setting.

01:24PM

10 Q. Well, but my point was a bit different. Does that mean at
11 times you actually do your own calculations by hand?

01:24PM

12 A. Yes. I have done extensive sets of calculations by hand
13 for the IVC filters that we're talking about.

14 Q. In this case, did you do some of those calculations by
15 hand?

01:25PM

16 A. Yes, I did.

17 Q. Did you also use finite element analysis, or FEA, for your
18 calculations?

19 A. Yes. I did FEA analysis as well as pencil and paper
20 calculations.

01:25PM

21 Q. And in doing that math, what kind of things can you do or
22 calculate specific to the things we're looking at in this case?

23 A. Well, one can do things like predict, if you know enough
24 about the device and the material involved, predict how the
25 device might break as a consequence of the loads and the

01:25PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 distortions that it experiences. And I can get out a paper
2 clip and make a little demonstration if I can find the paper
3 clip.

4 THE COURT: There's one there.

5 THE WITNESS: Thank you.

01:26PM

6 MR. STOLLER: Can we turn on the ELMO so the jury can
7 see?

8 THE COURT: Yes.

9 MR. STOLLER: Thank you, Your Honor.

10 THE WITNESS: So here's the paper clip. And if I know
11 enough about the steel that the paper clip is made from, I can
12 do things like predict the force it will take me to apply to
13 straighten it out like that. And then because I have got it
14 straightened out, now it's easier to do the demonstration. But
15 what I can do is bend it back and forth, and with a stress
16 analysis either done on a piece of paper or by FEA, I can
17 calculate what are called the stresses and strains in the
18 device. And from that information I can predict how long the
19 filter will last on average before it breaks.

01:26PM

01:26PM

20 BY MR. STOLLER:

01:26PM

21 Q. Or in this case how long the paper clip?

22 A. Yes. How long the paper clip will last before it breaks.

23 Q. You just mentioned stresses and strains. What are stresses
24 and strains?

25 A. Stresses and strains, stress is the intensity of the force

01:27PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 which is applied to an object. And I'm getting an elastic band
2 out. And so when I stretch the elastic band then I'm applying
3 a force to the elastic band. And a measure of that force
4 relative to the object is the stress. It's the force divided
5 by the area of the object.

01:27PM

6 The strain tells me about how much deformation is
7 going on. So when I stretch the rubber band I'm straining the
8 rubber band. And so strain is a measure of the intensity of
9 the deformation while stress is the measure of the intensity of
10 the force.

01:27PM

11 Q. So in doing the calculations to determine the sort of
12 forces that play in these on a rubber band or a paper clip or
13 an IVC filter, how do you use math to make those
14 determinations?

15 A. Well, there are formulary and there are equations and
16 there's information about the way that materials behave. And
17 you put that together in a calculation which makes sure that
18 the principles of balance of forces, as it's called, and the
19 way that the system deforms is properly modelled. And from
20 that modeling you carry out the calculation of the type that I
21 have been describing. And from the results of that
22 calculation, you can then make predictions about how the device
23 will respond whether it will break or whether it will survive
24 the sort of loads which are being applied to it.

01:28PM

01:28PM

25 Q. In this case -- well, let me ask this. So you can use the

01:28PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 math and determine what amount of force or stresses and strains
2 will result in the rubber band snapping?

3 A. Correct.

4 Q. And to do that sort of mathematical analysis, let's talk
5 specifically about this case, the calculations you did in the
6 finite element analysis. What sort of information do you need
7 to gather in order to determine how to put together the
8 calculation?

01:29PM

01:29PM

9 A. Well, what you need to gather is information about the
10 material that the device is composed of and also its shape and
11 dimensions and the environment within which the device will
12 operate. And one must also have an assessment of the possible
13 failure modes that the device will experience.

14 Q. When you say "failure modes" what do you mean?

15 A. I mean whether it will fracture, or in the case of the
16 filter, whether it will tilt; whether it will move within the
17 IVC, away from the position where it is first implanted; or
18 whether it will perforate through the wall of the IVC so that
19 some of it is sticking outside of the vena cava.

01:29PM

20 Q. Let's start where you started, which is you said the first
21 thing you need to understand is the device. What do you need
22 to understand about the device?

01:30PM

23 A. You need to understand the material that the device is made
24 of. And in the case of the filters that we're talking about,
25 the material is Nitinol. It's an alloy of nickel and titanium

01:30PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 and it's about 50 percent of each. And you need to understand
2 the way that that material behaves. And also concerning the
3 device, you need to know its shape and how the components are
4 assembled into the device as a whole and the dimensions of all
5 those features.

01:30PM

6 Q. What's important about material in terms of your analysis
7 and your math?

8 A. Well, in the case of Nitinol, it's a shape memory alloy.
9 It's also important that it's a superelastic material, and it's
10 also important in regard to what will happen to it that it has
11 what is called a fatigue limit so that eventually, it will
12 fracture because of fatigue, which is imposed on the material.

01:31PM

13 Q. What is fatigue limit?

14 A. So a fatigue limit, and again, I will demonstrate with my
15 paper clip. So fatigue is caused by loading and unloading a
16 device many, many times. So here I'm bending the paper clip,
17 I'm unloading it; I'm bending the paper clip, I'm unloading it.
18 And I can do that over and over again. If I bend it a lot, it
19 will -- I think you have probably all had this experience. If
20 you bend it a lot it will break quite quickly because of the
21 process of loading and unloading the material.

01:31PM

01:32PM

22 That process of damaging the material is called
23 fatigue, and the failure that eventually occurs is called
24 fatigue fracture.

25 Now, if I bend the paper clip just a little bit, it

01:32PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 will take me many, many unloadings and loadings of the paper
2 clip to cause it to break. And if I bend it by a very small
3 amount I can take the strains in the material below what's
4 called the fatigue limit. When the strains are below the
5 fatigue limit, the device, such as this paper clip, will last
6 tens of millions of loadings and unloadings.

01:32PM

7 And so the critical strain at which that becomes a
8 phenomenon of the device lasting tens of millions of loadings
9 and unloadings, that critical strain level is called the
10 fatigue limit.

01:33PM

11 Q. You have used a couple of times the terms "loading" and
12 "unloading." What do those mean?

13 A. Loading and unloading just means that there's some forces
14 applied to the device which cause it to bend or to deform in
15 some way, and then those loads are removed. It's the process
16 of that loading and unloading that causes the fatigue of the
17 material.

01:33PM

18 Q. And you mentioned with respect to Nitinol that one of the
19 important characteristics is that is a shape memory material.
20 Correct?

01:33PM

21 A. Correct.

22 Q. What does that mean to be a shape memory material?

23 A. A shape memory material is one that you can deform. For
24 example, if this was -- if the paper clip was made of Nitinol,
25 I could deform it like this at low temperature, and then if I

01:33PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 heat it up it would spring back to its original shape. In
2 fact, all the things I have been doing to it, it would reform
3 the shape of a paper clip. So that describes the behavior of a
4 shape memory alloy.

5 Q. And I believe the jury heard in opening statement that it 01:34PM
6 springs back into shape, is that an accurate portrayal?

7 A. Yes. It is also superelastic material, which means that if
8 you bend it a lot, and I have bent this paper clip a lot, it
9 will spring back to its original shape although it's been bent
10 a lot. That's quite different from the steel that this paper 01:34PM
11 clip is made of. It is not springing back to its original
12 shape.

13 Q. What does it mean to be a superelastic material?

14 A. So superelastic is the phenomenon that I just described,
15 but it is tied to the fact that when the material is deformed 01:34PM
16 the atoms within the material all go into a different order in
17 relation to each other. If you imagine a whole lot of people
18 standing shoulder to shoulder in a square pattern, if each row
19 takes a step forward it might be a diagonal pattern. And
20 that's the sort of thing that happens to the atoms when the 01:35PM
21 superelastic phenomenon takes place, and when you unload the
22 material, the atoms all go back to the original location and
23 that gives the material the very extensive springiness that is
24 one of the characteristics of the Nitinol.

25 Q. So in their different states the atoms are in a different 01:35PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 arrangement?

2 A. Correct.

3 Q. And they have different fatigue limits and different
4 reactions to strains and stresses in their different stages or
5 states?

01:35PM

6 A. Yes. In each state of the material the properties of the
7 material are somewhat different, and the properties in the
8 stretch state are different from the properties in the
9 unstretched state. And in addition, the question of how it
10 will respond to stress and strain is tied up to -- is tied up
11 with whether it's already stretched or whether it's not
12 stretched. So the behavior in different circumstances depend
13 on where it is in that superelastic response.

01:36PM

14 Q. And if we are talking about Nitinol, in particular the IVC
15 filters, what's important about those superelastic qualities?

01:36PM

16 A. Well, the superelastic quality means that you can put the
17 filter in a delivery tube and when you push it out, it will
18 spring out because it is a relatively -- because of the
19 extensive springiness of the material it will expand into the
20 IVC and press against the wall of the IVC because of its
21 springiness.

01:36PM

22 Q. And in coming to your opinions in this case about the
23 design of the IVC, the Eclipse IVC Filter and the testing
24 methods employed by Bard, did you take into account the
25 superelastic nature of the device?

01:37PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. Yes, I did.

2 Q. Let me ask you, you mentioned fatigue limits moment ago and
3 explained what they are. Do different materials have different
4 fatigue limits?

5 A. Yes, they do.

01:37PM

6 Q. Is that important in terms of the work you do or the
7 processes you undertook here?

8 A. Yes, it's very important because the fatigue limit is
9 information you need to know to compare the results of your
10 calculations with so that you can decide whether things are bad
11 or whether things are okay.

01:37PM

12 Q. What did you do to determine the fatigue limit of Nitinol
13 in this case?

14 A. I reviewed the scientific literature. I read papers that
15 summarize the results of experiments on Nitinol of similar
16 characteristics to the material that is used in the Bard IVC
17 filters. I also looked at information from manufacturers of
18 Nitinol and companies that use Nitinol in their devices, and
19 that includes reviewing the information in Bard documents
20 regarding the fatigue limit of Nitinol.

01:37PM

01:38PM

21 Q. Now, Bard hired an expert witness in this case, and he has
22 disagreement with you, Dr. Briant, he disagrees with you on the
23 fatigue limit of Nitinol. Is that correct?

24 A. That's correct.

25 Q. And he is critical of you that you didn't use Bard's

01:38PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 calculated number for the fatigue number of Nitinol. Is that
2 correct?

3 A. That's correct.

4 Q. Why don't you agree with Dr. Briant on that?

5 A. Well I disagree with him for a number of reasons. One of
6 them is that when you have failures occurring which are
7 attributed to fatigue, one must look very carefully at the
8 conditions which are involved in the system that you have
9 designed. But in addition, if you look at the data in the
10 literature, I found that the data from Bard is at the higher
11 end of the data concerning fatigue limits.

01:38PM

01:39PM

12 There is a large pool of data in the literature, and
13 what I found is that Bard's numbers were at the high end which
14 means that the material in terms of comparison with similar
15 materials, is more resistant to fatigue fracture than the
16 similar materials which it is being compared with. And I also
17 know from experience with other companies who make Nitinol
18 devices, that the conditions that are experienced by devices
19 such as heart valves and IVC filters are such that the fatigue
20 limit is likely to be less than the value that Bard assumed
21 would be appropriate for analyzing their device, and therefore,
22 I took into account the comprehensive information available in
23 regard to fatigue limit instead of just relying on Bard's data
24 that they obtained after limited testing of their material.

01:39PM

01:39PM

25 Q. What's the difference between -- I think you said this but

01:40PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 just to make the point clear -- what's the difference between
2 the fatigue limit and the data and information that you relied
3 on versus the data and information that Bard used?

4 A. Well, Bard obtained the data for their Nitinol from tests
5 that their associated organizations carried out for them, and 01:40PM
6 they carried out limited tests in a specific way. The testing
7 that is recorded in the literature involves a much more diverse
8 set of ways of testing the material and, therefore, gives you a
9 much more comprehensive assessment of the fatigue properties of
10 Nitinol. And as I said, the indication is that the material or 01:41PM
11 the data that Bard obtained suggested that their material was
12 substantially more fatigue resistant than material which is
13 essentially identical that is used for the tests that are
14 published in the literature and used by other medical device
15 implant companies. 01:41PM

16 Q. And when you say "more resistant to fatigue" what does that
17 mean?

18 A. More resistant to fatigue means that the device will last
19 longer at a given level of strain, or that you can apply a
20 higher strain and have the device last for tens of millions of 01:41PM
21 loadings and unloadings.

22 Q. Is that a reasonable practice or assumption to take when
23 calculating worst-case scenarios?

24 A. Yes, it definitely is, especially when it is clear that
25 failures by fatigue are happening in a given device that you 01:42PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 are trying to redesign.

2 Q. Let me make sure I understand what my question was.

3 Is Bard's reliance on that higher fatigue resistance
4 number reasonable under worst-case testing conditions?

5 A. No. It was not reasonable for them to rely on those data. 01:42PM

6 Q. Because why?

7 A. Because it suggested the Nitinol that they were using had a
8 relatively high resistance to fatigue fracture whereas evidence
9 in the literature was contrary to their assumptions and that
10 similar Nitinol would be much more likely to suffer fatigue
11 failures than they were assuming. 01:42PM

12 Q. More likely to break?

13 A. More likely to break.

14 Q. You mentioned that the shape and dimensions of the filter
15 are important. Why are those important? 01:43PM

16 A. Well, the shape and dimensions are important because one
17 needs to look at how the device will respond to loads which are
18 applied to it and the situation that generates those levels of
19 stress which are likely to cause the device to have a problem
20 are associated with its shape. 01:43PM

21 And I can demonstrate that with a plastic fork. If I
22 pull on the tine, it will always break at the top of the tine,
23 and that's associated with the way that the fork is designed
24 and the way that the shape is patterned into the material in
25 such a way that it makes the top of the tine a vulnerable 01:44PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 location when I bend the tine in the way that I just
2 demonstrated.

3 Q. So in your demonstration there, you would predict based on
4 the design and shape and dimensions of the fork that it is
5 going to break where it broke?

01:44PM

6 A. Yes. That is correct.

7 Q. Is that important to understand when you are designing an
8 IVC filter?

9 A. Yes, because the place where it is most probably going to
10 break is the worst location, the worst-case location in the
11 device, and it's important to identify where that location is.
12 And the shape and dimensions of the device, the filter, are
13 what determine that.

01:44PM

14 Q. What are important about the shape and dimensions of the
15 Eclipse IVC Filter?

01:44PM

16 A. Well, the Eclipse IVC Filter, and I have one here, the
17 features which are important in regard to its dimensions and
18 its shape are that if you look at it from the top, you can see
19 that there's a certain width to the span between its feet at
20 the bottom, and that's approximately 40 millimeters in this
21 case; and also the span between the hands which are at the end
22 of the bent limbs on the filter, so I'm calling them the hands
23 down at this end. And the span between the hands is an
24 important dimension. The fact that the arms and the legs are
25 very thin, they are about a third of a millimeter in thickness,

01:45PM

01:45PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 and the fact that the limbs have the shape that they do, the
2 arms are slightly bent and the legs are a bit straighter. And
3 then also, that the limbs are all gathered into the top, which
4 is a cap, which I will lift it up closer to the lens and you
5 can see that the limbs all go into a cap at the top of the
6 filter.

01:46PM

7 And if I draw a quick sketch of the cap where the
8 limbs go in, so I have drawn cross-sectional view, the limbs
9 come in like this and this location here where the limbs are
10 adjacent to the mouth of the cap, can be a very important area.
11 If the limbs move over and press against the edge that can
12 cause a very significant increase in the strains that the limbs
13 experience in a location which is already the worst-case
14 location for the stresses and the strains which are present in
15 the limbs.

01:46PM

01:47PM

16 So in other words, even before you get this
17 concentrating effect, this is already the bad area in terms of
18 likelihood of fracture and the interference between the limb
19 and the cap can make that problem significantly worse.

20 Q. And in the drawing that you have done there, Doctor, the
21 two lines that are coming out of what I will call the
22 horseshoe, are those the arm?

01:47PM

23 A. Yeah. This so this is an arm which is going down below the
24 filter. And this is the cap at the top. And I left out the
25 hook which is on the top of the cap.

01:47PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Q. And so that's a design feature that's important to you in
2 your analysis of this filter?

3 A. Yes. Correct.

4 Q. Let's talk a little bit about the environment because you
5 mentioned the environment in which the device sits or the IVC
6 filter sits. What's important to understand about the
7 environment?

01:48PM

8 A. Well, what's important is the configuration of the
9 environment, so what does the vena cava look like in terms of
10 size and shape; what it does in terms of its movement and
11 actions, and it's a very dynamic environment, and for the kind
12 of forces and changes of shape that the IVC can force on the
13 filter while it's implanted in the vena cava.

01:48PM

14 Q. Is the material of the vena cava important to understand?

15 A. Yes. The material of the vena cava and the tissues and
16 organs around it are important to understand in terms of what
17 its interaction with the filter will be and its relative
18 stiffness compared to the stiffness of the filter.

01:48PM

19 Q. Why is that important?

20 A. Because the relative stiffness will determine how much the
21 filter gets squeezed when squeezing action takes place in the
22 abdomen. And the squeezing action takes place even when you
23 breathe because your diaphragm moves up and down and that
24 squeezes the contents of your abdomen and presses on the vena
25 cava and will make the vena cava get smaller when the diaphragm

01:49PM

01:49PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 is going down.

2 So these are all aspects of what is important, and if
3 the surroundings of the vena cava are pressing on the vena
4 cava, if the filter is very, very stiff, it will resist the
5 compression of the organs and tissue around the vena cava. But
6 if the filter is relatively compliant compared to the contents
7 around the vena cava then the filter will not be able to resist
8 the squeezing action of the contents of the abdomen.

01:50PM

9 Q. What's important about the shape and dimensions of the
10 inferior vena cava to the -- well, let me step back a minute.

01:50PM

11 The jury saw yesterday in opening statements a couple
12 of different animations of the filter sitting in an IVC and I
13 think they were fairly static and non-movable IVCs.

14 What's significant in terms of your analysis of the
15 design and the testing that was done with respect to the IVC
16 filters about the shape, the dimensions of the IVC, and how it
17 acts?

01:50PM

18 A. Well, so the IVC, which you can think of as the red circle,
19 is what I have drawn on this diagram. And the outer blue
20 circle is the width of the filter before it's squeezed into the
21 vena cava. So you have to squeeze the filter into the vena
22 cava when you are implanting it to get it to fit. And the
23 phenomenon which are important, or the aspects of this which
24 are important are that the shape and size of the vena cava will
25 be important as to whether the IVC filter will tilt or whether

01:51PM

01:51PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 it will perforate the wall of the IVC or whether it will
2 experience loading and unloading to an extent that will cause
3 fatigue fracture problems for the filter.

4 Q. And I believe Mr. North showed the jury a picture of the
5 IVC and described it as twisting and turning and stretching.

01:52PM

6 Do those have an impact on your analysis and the design of this
7 filter?

8 A. Yes. It's a very dynamic environment, and all those
9 movements and actions will cause the filter to do various
10 things. For example, it can cause the filter to tilt. It can
11 cause the filter to move, especially downwards in the case of
12 the Eclipse Filter, it tends to move down because of the
13 dynamic environment and the forces which are applied to it.

01:52PM

14 And it can cause -- it can help to induce tilting in the
15 filter. And then the expansion and contraction that takes
16 place is exactly the kind of loading and unloading that will
17 trigger fatigue problems in the device as a consequence of the
18 environment within which it is implanted.

01:52PM

19 Q. Are there other -- any other relevant characteristics of
20 the environment which the filter is going to sit that affect
21 your analysis in this case?

01:53PM

22 A. Well, the one of the features of tissue is that it tends to
23 glue itself to bodies which are present in the human body. And
24 so the tissue of the wall of the vena cava will tend to glue
25 itself and grow over the limbs of the filter. And this kind of

01:53PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 behavior can affect how the filter responds. This kind of
2 feature can affect how the filter responds.

3 Q. And I believe the jury has heard the term
4 endothelialization, correct?

5 A. That's what I just described is the phenomenon of
6 endothelialization.

01:53PM

7 Q. How does that affect the stresses and strains that you have
8 analyzed here?

9 A. It will generally increase the level of stresses and
10 strains which are present in the device. And I can demonstrate
11 that using my arm. If my arm is loose and I try to turn my
12 hand, I can do that quite freely. But if I glue my left hand
13 to my right hand and now I try and rotate my right hand, I can
14 feel that there are forces within my arm which are generated
15 just because I have stopped my arm from moving.

01:54PM

01:54PM

16 So it's that kind of effect which can make the strains
17 and stresses higher in the filter compared to when
18 endothelialization is not present.

19 Q. You talked a bit ago about understanding of failure modes
20 or complications associated with the device. Why is that
21 important?

01:54PM

22 A. Could you repeat the question?

23 Q. Sure. Earlier when I asked you questions about what are
24 the important things you need to consider in analyzing the
25 testing and designing of a product, one of the things you

01:55PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 identified was the failure modes or complications.

2 Do you recall that?

3 A. Yes, I did. I do.

4 Q. And my question was, what's important about that for that
5 process?

01:55PM

6 A. What's important about that is that in carrying out the
7 tests and carrying out the calculations one must have a good
8 idea of the failure modes so that you can assess whether they
9 are likely to occur after the filter has been implanted in the
10 human body.

01:55PM

11 MR. STOLLER: Gay, would you put up 5447 again? Thank
12 you.

13 Doctor, this is Exhibit 4557, which is the summary of
14 your opinions that we discussed before.

15 Your Honor, may we now publish this to the jury?

01:56PM

16 MR. NORTH: No objection, Your Honor.

17 THE COURT: Yes.

18 BY MR. STOLLER:

19 Q. This is a summary of your opinions, correct?

20 A. Correct.

01:56PM

21 Q. I don't want to go through them again because we talked
22 about them at the outset and I'd like to be conscientious of
23 people's time.

24 I'd like to talk to you about -- start with Opinion
25 Number 1, what is your first opinion in this case?

01:56PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. The filter is defectively designed, and that's what causes
2 it to tilt, perforate, and move within the vena cava and to
3 fracture and lose components by fracture.

4 Q. We're talking today and here in this case about the Eclipse
5 IVC Filter. Do you understand that?

01:56PM

6 A. Correct. Yes.

7 Q. And the example filter you showed the jury, is that an
8 Eclipse?

9 A. That is an Eclipse.

10 Q. And there's been talk -- the jury's already heard about the
11 Recovery device, the G2, the G2X, and the Eclipse. What are
12 the differences between the Eclipse and the G2?

01:56PM

13 A. The Eclipse is mechanically and materially identical to the
14 G2, the G2 Express. The G2 express is the device that has the
15 hook on top, and that's the only difference between the Express
16 and the G2.

01:57PM

17 So the only difference between the Eclipse and the G2
18 models apart from the hook at the top absent in the G2 is that
19 the surface of the Eclipse is polished. It's polished by an
20 electrical method called electropolishing, and it has a
21 slightly different color is another aspect of its appearance.

01:57PM

22 MR. STOLLER: I was going to ask, can we turn on the
23 ELMO so he can show the jury while he's talking, Your Honor?

24 THE COURT: Yes.

25 MR. STOLLER: Thank you.

01:58PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 BY MR. STOLLER:

2 Q. I'm sorry. Would you point out those design features again
3 so the jury can see?

4 A. So in terms of its shape and size and configuration, the
5 Eclipse is identical to the G2 Express. It's mechanically and 01:58PM
6 materially identical to the G2 Express. The G2 Express differs
7 from the G2 only by the fact that there's this hook, this
8 retrieval hook on the top of the cap. And the only difference
9 therefore of significance between the G2 and the Eclipse in
10 terms of my concerns is that the surface is electropolished on 01:58PM
11 the Eclipse.

12 Q. You mentioned it's also blue?

13 A. And it's also blue compared to a silvery color in the case
14 of the G2.

15 Q. Is your analysis of the design defect for the Eclipse the 01:59PM
16 same as it is for the G2?

17 A. Yes. In terms of tilt, caudal movement, movement of the
18 filter in the IVC, and fracture, the analysis and the
19 assessment is identical for the G2 and the Eclipse because
20 these features that were changed, the only feature that was 01:59PM
21 changed, the surface polishing, is irrelevant to the question
22 of whether the filter will tilt or whether it will migrate
23 within the vena cava.

24 And I should correct something. There would be a
25 marginal improvement in the fracture performance of the device 01:59PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 because the polishing is meant to address that issue.

2 The question of what the forces are that the filter
3 applies to the wall of the IVC is unchanged in the same
4 circumstances, and therefore, the tendency for the filter to
5 penetrate and perforate through the wall of the IVC is
6 unchanged by the process of electropolishing.

02:00PM

7 The electropolishing smooths the surface of the
8 material which in principle will improve the fatigue properties
9 of the material, however, the improvement in the fatigue
10 properties is relatively small, and it is relatively small
11 compared to the large strains that the filter can experience as
12 a consequence of the kind of displacements and forces which are
13 applied to it by the IVC. And so my assessment is that the
14 fatigue properties, the fatigue fracture properties are only
15 marginally improved by the process of electropolishing.

02:00PM

02:01PM

16 Q. Does this change of electropolishing affect your opinions
17 with respect to the design leading to tilt?

18 A. No.

19 Q. Does it affect any of your opinions with respect to the
20 design leading to perforation?

02:01PM

21 A. No. It makes no difference.

22 Q. How about the design with respect to the moving or
23 migration of the filter?

24 A. It makes no difference.

25 Q. Let's talk about those last three first then we'll come

02:01PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 back to fracture.

2 What's the basis for your opinion that the design of
3 this filter leads to tilt?

4 A. Well, the basis is that the filter in this regard is simply
5 a spring. And I have a coil spring to show you. I have to be 02:01PM
6 careful so it doesn't spring all over the courtroom. But you
7 see when we squeeze a spring of course we have to apply forces.
8 And when I let go the spring wants to come back to the length
9 it originally was. And in that regard, the filter is simply a
10 spring so that when I push the arms together at the hands, I 02:02PM
11 have to apply forces to make that happen. And when I let go,
12 the arms spring back to the width that they originally had.

13 So the spring in that -- sorry, the filter in that
14 sense is acting simply like a spring and springs always want to
15 expand back to their preferred length, their original length. 02:02PM

16 And again, if I make use of this illustration, as I
17 was saying earlier, think of the red as the wall of the IVC and
18 the outer perimeter of the blue area as the place where the
19 hands of the arms like to sit. And so when I implant the
20 filter in the IVC, the filter is squeezed, and one way that it 02:03PM
21 can relax itself to try to get back to the original width is by
22 tilting.

23 Q. The red on the blue is a little hard for me to see, is it
24 possible -- I don't know if it is for anybody else. Could you
25 perhaps draw that circle and show me what you are talking 02:03PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 about?

2 A. Yes. So there's the two circles, and so this is the IVC
3 wall. And the arms, the feet, the hands of the filter, when
4 it's in its natural shape, would be sitting there and now to
5 get the filter inside the IVC, it's not long enough, to get the
6 filter inside the IVC I have to squeeze the hands and the feet
7 together and it wants to expand back to its original width and
8 it can do so by tilting.

02:04PM

9 Q. And you prepared a demonstrative to show that to the jury,
10 have you, Doctor?

02:04PM

11 A. Yes, I have.

12 MR. STOLLER: Gay, would you pull up 4342, please.

13 Doctor, is this that demonstrative?

14 THE WITNESS: That is.

15 MR. STOLLER: Your Honor, may we show this to the
16 jury?

02:04PM

17 MR. NORTH: No objection, Your Honor.

18 THE COURT: Yes.

19 MR. STOLLER: Thank you, Gay.

20 BY MR. STOLLER:

02:05PM

21 Q. Doctor, would you explain to the jury what you're
22 demonstrating with this exhibit?

23 A. Yes. What you are seeing on the left-hand side is a filter
24 which is not tilted, and it is sitting nice and straight up and
25 down in the vena cava. And on the right is a filter that has

02:05PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 tilted, and that's the process that we're talking about in
2 regard to how the filter responds when it tries to expand its
3 width.

4 Q. And you have done a drawing as well.

5 MR. STOLLER: Gay, would you pull up 4372? 4373? 02:05PM
6 Mine has 2 but maybe I'm wrong. If you pull it up maybe we'll
7 see.

8 As usual, you are better than I am. Thank you, Gay.

9 BY MR. STOLLER:

10 Q. Doctor, is this an illustration that you have drawn to 02:06PM
11 prove this point?

12 A. Yes.

13 MR. STOLLER: Your Honor, may we show this to the
14 jury?

15 MR. NORTH: No objection. 02:06PM

16 THE COURT: Yes.

17 MR. STOLLER: Thank you.

18 BY MR. STOLLER:

19 Q. Doctor, what are you showing through this illustration?

20 A. I'm showing through the illustration I drew myself so they 02:06PM
21 are not as pretty as the previous illustrations, but what this
22 illustrates again is an untilted filter on the left and a
23 tilted filter on the right. And in the case of the untilted
24 filter on the left, line A-B is the line between the hands of a
25 pair of arms. And on the right the line that joins the hands 02:06PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 of the pair of arms is now a C, and you can see that we are
2 moving at -- we are going across the vena cava in a somewhat
3 diagonal manner. And as I think you know when you cross a road
4 in a diagonal manner you have to walk a lot farther than when
5 you go straight across the road.

02:07PM

6 So what that's illustrating is the distance from A to
7 C is bigger than the distance from A to B, so the filter has
8 expanded as a spring in the process of tilting.

9 Q. How is the filter able to do that >how is it able to move
10 like that?

02:07PM

11 A. Well, the filter is acted on by forces in the vena cava
12 that might jiggle it around and that process might initiate the
13 process of tilting. And the tilting process drives itself
14 because of the expansion of the spring, but the process of
15 movement of the vena cava and the dynamic environment will aid
16 that instability.

02:07PM

17 Q. Did you perform mathematical calculations to confirm this
18 opinion that the IVC filter will tilt?

19 A. Yes, I did.

20 Q. Did you also perform finite element analysis?

02:08PM

21 A. Yes, I did.

22 Q. And did that also confirm that the IVC filter will tilt?

23 A. Yes, it did.

24 Q. How did you do that, those calculations and that FEA?

25 A. Well, in the FEA, I put a filter in the IVC and I implanted

02:08PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 it in a way that is illustrated in the previous illustration
2 that you were shown. And I then pushed on the head of the
3 filter to see how it would respond. And in the computer I
4 calculated the forces and the deformations that would be
5 required for that process and I found that you actually have to 02:08PM
6 hold the filter back to stop it from tilting. And that shows
7 that it wants to tilt and it wants to expand, and it wants
8 to -- it is unstable.

9 MR. STOLLER: Gay, would you bring of 4342 again,
10 please? 02:09PM

11 BY MR. STOLLER:

12 Q. This is the demonstrative we just looked at before, Doctor.
13 And this drawing is a -- you created a computer model of it, am
14 I to understand that correctly?

15 A. Yes. It's a graphic. It's not exactly my computer model. 02:09PM
16 But it's a graphic that illustrates the computer model that I
17 used. And you can see that the purple is the wall of the IVC
18 and the IVC model is being relatively stiff in this particular
19 calculation.

20 Q. And based on all of your calculations that you did by hand 02:09PM
21 and the FEA analysis that you did as well as your engineering
22 background in looking at this design, what conclusion did you
23 come to?

24 A. I came to the conclusion that the filter wants to tilt and
25 it is very unlikely that it will stay straight up and down in 02:10PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 the vena cava.

2 Q. Let's talk about your opinions with respect to the filter.

3 We used the term perforate. It means puncturing through the
4 IVC. What's your opinion with respect to that issue in this
5 case?

02:10PM

6 A. That the design of the filter makes perforation likely to
7 occur, probably will occur, in the case of this design of the
8 filter.

9 Q. Why is that?

10 A. Because it's essentially the same reason that the filter
11 wants to tilt because it wants to expand. And the way that it
12 can expand is by cutting through the wall of the vena cava.
13 And a feature that contributes to this process is the fact that
14 the limbs of the filter are very thin, and therefore, is
15 relatively easy to make them cut through the wall of the IVC.
16 And in certain situations, the tip of the limbs can interact
17 with the wall of the IVC just as a needle being poked into the
18 wall of the IVC would go into the wall of the IVC and therefore
19 puncture through the wall of the IVC.

02:10PM

02:11PM

20 MR. STOLLER: Gay, would you pull up 4349, please?

02:11PM

21 BY MR. STOLLER:

22 Q. Doctor, is this a demonstrative that you have prepared to
23 illustrate your opinions with respect to perforation by the
24 filter?

25 A. Yes, this is.

02:11PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 MR. STOLLER: Your Honor, may we display this to the
2 jury?

3 MR. NORTH: No objection, Your Honor.

4 THE COURT: Yes.

5 MR. STOLLER: Thank you.

02:11PM

6 BY MR. STOLLER:

7 Q. And would you explain to the jury what this is?

8 A. Oh. This is a result from a calculation that I did in the
9 computer, and it shows a filter in the vena cava. But in this
10 case, three of the legs, and the they are the ones that are
11 sticking outside of the right and side of the diagram, three of
12 the legs have perforated through the wall of the vena cava.
13 There's only two visible because one is hidden behind another
14 one.

02:12PM

15 And the consequence of the -- of this perforation is
16 that the forces on the filter become unbalanced and that is
17 leading to tilting as well as -- leading to tilting that's
18 following the perforation process which has occurred.

02:12PM

19 Q. So perforation will lead to tilt?

20 A. Yes.

02:12PM

21 Q. And tilt will lead to perforation?

22 A. Correct.

23 Q. And that's demonstrated by this demonstrative Exhibit 4349?

24 A. That's correct.

25 Q. Let's talk next, if you would, about your opinions with

02:13PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 respect to the Eclipse and movement of the filter. What's the
2 basis for your opinion that the design of the filter leads to
3 migration?

4 A. Well, can we go back two slides before, please?

5 MR. STOLLER: Gay, would you please find 4342.

02:13PM

6 BY MR. STOLLER:

7 Q. This one?

8 A. Yes. So my assessment is that tilting contributes to the
9 movement, and what you can see in this illustration is that,
10 well, it's not quite drawn correctly, but that what would
11 happen is that the filter would rotate around one of its feet
12 and that action would move the filter down by a slight amount.
13 And then that process could happen again and again and again,
14 especially in the dynamic environment of the IVC so the
15 conditions could be repeated over and over again such that
16 continued tilting in opposite directions would occur and the
17 filter can walk down the IVC towards your feet.

02:13PM

02:14PM

18 Q. By "walk down" you mean tilt and tilt and tilt?

19 A. Tilt, tilt, tilt.

20 Q. Let's talk, Dr. McMeeking, about your opinions about the
21 Eclipse Filter and its susceptibility to fracture. What are
22 your opinions with respect to that?

02:14PM

23 A. My opinion is that the design of the filter leads to its
24 fracture in terms of fatigue as a consequence of the forces and
25 motions that it experiences within the IVC.

02:15PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Q. What is the basis for that opinion?

2 A. The basis of that opinion are calculations that I carried
3 out in which I calculated the strains that the filter would
4 experience in different circumstances and compared them with
5 fatigue limits of the material and found that in some
6 circumstances, in many circumstances, that the strain would
7 exceed the fatigue limit and, therefore, fracture would
8 eventually ensue.

02:15PM

9 Q. So you did hand calculations and finite analysis?

10 A. Yes. I did hand calculations and finite element
11 calculations.

02:15PM

12 Q. Did you do these based upon worst-case conditions?

13 A. Yes. I did them in a variety of worst-case conditions and
14 observed that in many circumstances, the strains were high
15 enough that the fatigue failure would occur within the useful
16 lifetime of the device.

02:16PM

17 Q. What are the relevant factors leading to your conclusion
18 that these devices are likely to fracture?

19 A. Well, an observation is that tilting will increase the
20 strains that the filter experiences, and therefore, will make
21 it more likely that the fatigue failure will occur. And
22 endothelialization will have similar effect and would elevate
23 the strains so that the fatigue fracture will be more likely.
24 And perforation will increase the strains of the filter
25 experiences, and that also will contribute to making fatigue

02:16PM

02:16PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 fracture more likely.

2 Q. So under situations where a filter is tilted, perforated,
3 and endothelialized you calculated its likelihood of failing to
4 fatigue?

5 A. That's correct.

02:17PM

6 Q. And concluded what?

7 A. And concluded that it would eventually break after a
8 certain number of cycles of loading, and the pieces could break
9 off and become separated from the filter.

10 Q. Do those things actually happen? Do filters tilt,
11 perforate, and endothelialize?

02:17PM

12 A. Yes. There's observations that the G2 family of filters
13 all experience tilting, perforation, and fracture of its limbs.

14 Q. And if we were to look at the filter that's in Exhibit 4342
15 in front of you, are there places that are more likely to
16 fracture than others?

02:17PM

17 A. Yeah. The place that is most likely to fracture in the G2
18 filter is up at the top of the arm where the arm is going into
19 the cap at the top.

20 Q. And is that also true with the Eclipse?

02:18PM

21 A. It's true of the Eclipse as well.

22 Q. And you said that there were some differences you found in
23 terms of the resistance to fracture in the Eclipse Filter as
24 distinct from the G2 Filter.

25 Did you also conclude that like the G2 Filter the

02:18PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Eclipse Filter is likely to break under those situations?

2 A. Yes. I concluded that under conditions of tilting and
3 perforation and endothelialization that the strains in the
4 Eclipse Filter would still be high enough that they would
5 exceed the fatigue limit and, therefore, make fatigue fracture
6 occur.

02:18PM

7 Q. And what difference, if any, does the -- I'm sorry -- does
8 the electropolishing make in this circumstance?

9 A. Well, the electropolishing increases the fatigue limit by a
10 modest amount, by about .2 percent of strain. And therefore,
11 compared to the levels of strain which occur in the Eclipse
12 Filter, this increase is quite marginal and, therefore, not
13 enough to fend off the problems of fatigue that the filter was
14 experiencing.

02:19PM

15 Q. Now, we talked a bit ago about Dr. Briant, Bard's
16 professional -- I'm sorry -- their expert witness. And he
17 criticizes your analysis of fracture. Correct?

02:19PM

18 A. Correct.

19 Q. And what's his criticism of your analysis?

20 A. Well, he criticizes my analysis of fracture because he
21 asserts that I use conditions which are beyond the level of
22 what would be expected for worst-case conditions.

02:19PM

23 Q. Does he criticize your use of -- I think one of the things
24 he said is that you don't use a superelastic property in
25 analyzing this. Is that correct?

02:20PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. That's correct. He criticizes me for using what's called
2 linearlastic response of the filter rather than using
3 superelastic response of the material.

4 Q. And how do you respond to Dr. Briant?

5 A. Well, I respond to that by the observation that --

02:20PM

6 Q. Before you start, you are showing the filter.

7 MR. STOLLER: Your Honor, may we use the ELMO for him
8 to show the jury?

9 THE COURT: Yes.

10 MR. STOLLER: Thank you.

02:20PM

11 THE WITNESS: So I respond to that by observing that
12 in certain circumstances, that superelastic behavior is clearly
13 important. For example, when you are compressing the filter
14 severely, and I don't want to compress it too much, but when
15 you are compressing it severely such as when you put it in the
16 delivery tube and then push it back out to the delivery tube,
17 of the significant springiness associated with the superelastic
18 behavior is important.

02:21PM

19 But in other circumstances, for example, once you have
20 got the filter in the vena cava and it is being squeezed by
21 relatively small amounts, then the response of the material is
22 what we call linearlastic which is a smaller strain, it's a
23 smaller movement response of the material that arises in that
24 circumstance.

02:21PM

25 And so for the purpose of doing fatigue calculations,

02:21PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 the linearlastic response is what matters, and the superelastic
2 response in this process is irrelevant.

3 BY MR. STOLLER:

4 Q. So when you were analyzing the fatigue over time, it's
5 based on your calculations of normal breathing activities?

02:22PM

6 A. That's correct.

7 Q. And so if the filter becomes tilted, perforated,
8 endothelialized, then normal breathing circumstances themselves
9 can create sufficient stress and strain to ultimately cause a
10 fracture?

02:22PM

11 A. That's correct, yes.

12 Q. Dr. Briant also says that your calculations and your FEA
13 results only take into account a single arm of the filter, is
14 that correct?

15 A. That's correct, yes.

02:22PM

16 Q. Is that a problem?

17 A. No. It's not a problem.

18 Q. Why not?

19 A. Because when doing fatigue calculations, you concentrate on
20 the worst-case location so that you can identify what
21 conditions there will cause the fatigue fracture. And as I
22 indicated, the worst-case location in the G2 family of filters
23 is up near the cap in the arms just where the arms come out of
24 the cap. And to understand what is happening to the arms in
25 that regard, it is sufficient to analyze only one arm, and that

02:22PM

02:23PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 one arm is representative of the behavior of all the other
2 arms. Or to put it another way, by doing a calculation for one
3 arm you are doing a calculation for six arms. And furthermore,
4 what the legs do is not relevant.

5 So it's a completely valid calculation to look at one
6 arm at a time and do the calculation. And, in fact, it's even
7 consistent to leave out bits of the arm and only focus on the
8 portion that is experiencing the strains and stresses that you
9 are worrying about to undertake the calculation which is
10 necessary.

11 Q. And Bard conducted some FEA analyses of its own, correct?

12 A. Yes.

13 Q. And in some of those did it analyze just a single arm?

14 A. Yes. In many of their calculations they analyzed only a
15 single arm.

16 Q. When you teach these sort of analyses to students, both
17 undergrad and those who are going to themselves become doctors
18 of engineering, do you teach them the same principles and same
19 method you have used here?

20 A. Yes, I do. Yes.

21 Q. Dr. Briant also criticizes your analysis by saying that you
22 don't explicitly include the surrounding tissue in your
23 analysis. Is that true?

24 A. That's correct.

25 Q. Is it true that you don't include that surrounding material

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 in your analysis?

2 A. No. That's not true. What I did was I made an assessment
3 of the relative stiffness of the surrounding environment around
4 the IVC, and I came to the assessment that it is relatively
5 stiff compared to the filter, and therefore, one can treat the
6 environment as an IVC which neglects the possible response of
7 the tissues and organs around it in a way that it interacts
8 with the filter.

02:25PM

9 Q. We talked earlier about one of the things you need to do in
10 doing these sort of analyses and designing devices is
11 understanding the environment. What's the basis for your
12 concluding the stiffness of this environment?

02:25PM

13 A. Well, there's -- first of all, the abdomen is full of
14 organs and material and tissue and so on. And so it's fairly
15 -- it's well packed with stuff, and therefore, it is difficult
16 to move things out of the way and have it not compress the vena
17 cava even if a filter is trying to resist that compression. So
18 that's one observation that enabled me to make the assessment
19 that I did.

02:25PM

20 But in addition, there are data in the literature that
21 indicate that the surrounding tissues and organs are relatively
22 stiff compared to filters when they are interacting with the
23 vena cava filters.

02:26PM

24 Q. We mentioned Bard did their own FEA analyses. Did they
25 assume the surrounding area and environment was stiff, or did

02:26PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 they assume it was soft like Dr. Briant?

2 A. They assumed it was stiff.

3 Q. And if we were to assume the surrounding environment was
4 soft like Dr. Briant, is that best-case or worst-case scenario
5 for the filters?

02:26PM

6 A. That's a best case, a favorable case for the filter.

7 Q. Less likely to fracture?

8 A. Less likely to fracture.

9 Q. And both you and Bard assume in your analysis that it is,
10 in fact, stiff?

02:26PM

11 A. Yes. Correct.

12 Q. Is there a fundamental difference between your analysis and
13 Dr. Briant's analysis in this case?

14 A. There's no fundamental difference in terms of the actual
15 calculations which are carried out in the method used to carry
16 them out. The fundamental difference is the assumptions that
17 underlie the way that the calculations are done and set up.

02:27PM

18 Q. And what were Dr. Briant's assumptions?

19 A. Dr. Briant's assumptions were that nothing very bad would
20 happen to the filter and that the conditions it would
21 experience would be quite favorable in terms of allowing its
22 avoidance of failure modes.

02:27PM

23 Q. In conducting analysis to determine whether or not a filter
24 is likely to suffer fractures, was that a reasonable analysis
25 by Dr. Briant?

02:27PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. No.

2 Q. Why not?

3 A. Because it didn't make sure that worst-case conditions were
4 present in the way that the filter responded to what was
5 happening to it within the IVC. It didn't account for the
6 constraints of how severe endothelialization can affect the way
7 that the filter responds. It didn't account for how
8 significantly the effect of perforation can affect the filter.
9 And it didn't look at how significantly the effect of tilt
10 could affect the strains on the filter.

02:28PM

02:28PM

11 Q. Do his assumptions comply with the standards for safe and
12 reliable design?

13 A. No.

14 Q. Was your analysis reasonable?

15 A. Yes.

02:28PM

16 Q. Was it accurate based on the conditions that you described?

17 A. Yes.

18 Q. Let me ask you, if you would, and you have got the filter
19 there, could you describe for the jury the specific design
20 defects that exist in that design of the Eclipse Filter?

02:29PM

21 A. Well, the conical shape is a basic defect. The thinness of
22 the arms is a basic defect. The cap design that I mentioned
23 earlier where the arms enter the cap is a basic defect in the
24 design. And -- yes.

25 Q. How about the stiffness or the resistance to movement of

02:29PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 the -- or fatigue of the arms and legs themselves?

2 A. Well, yeah, the arms and legs are designed so that they are
3 very susceptible to fatigue. And that's tied up with their
4 shape and orientation and the fact that they can perforate the
5 wall of the IVC. And that leads to enhanced likelihood of
6 fracture by fatigue.

02:29PM

7 MR. STOLLER: Gay, would you find Exhibit 4559,
8 please.

9 THE COURT: We're going to break at this point, Mr.
10 Stoller. We will take a break until 2:45. Ladies and
11 Gentlemen, we'll excuse you at this time.

02:30PM

12 MR. STOLLER: Thank you, Your Honor.

13 (Recess from 2:30 p.m. until 2:47 p.m.)

14 THE COURT: Go ahead, Mr. Stoller.

15 MR. STOLLER: Thank you, Your Honor.

02:47PM

16 BY MR. STOLLER:

17 Q. Dr. McMeeking, just before we broke we were talking about
18 your opinions with respect to the defective -- the design
19 defects in the Eclipse Filter. And you identified the conical
20 design, the thin needle-like limbs in the arms and legs that
21 lead to perforation, the design concentration -- the design
22 that concentrates the strain mentioned at the shoulder or the
23 elbow where the filter meets the cap.

02:47PM

24 Are there any alternative design elements that you
25 have identified that would help relieve or ameliorate some of

02:47PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 the issues?

2 MR. NORTH: Your Honor, objection. That's outside the
3 scope of the report.

4 THE COURT: Is that in the report, Mr. Stoller?

5 MR. STOLLER: It is in the report.

02:47PM

6 THE COURT: All right. Could I have a copy and have
7 you show that to me? Why don't you approach, counsel, and we
8 can talk about that.

9 Ladies and Gentlemen, if you want to stand up feel
10 free.

02:48PM

11 (Discussion was had at sidebar out of the hearing of
12 the jury:)

13 THE COURT: By the way, while we're looking for that,
14 the jurors, while they were coming back in, asked Traci if they
15 could hold the filter, if it could be passed around so they
16 could each hold it and look at it.

02:48PM

17 MR. STOLLER: This is Dr. McMeeking's filter so we
18 will have to ask him.

19 MR. NORTH: It has to be admitted into evidence,
20 doesn't it?

02:48PM

21 MR. STOLLER: No.

22 THE COURT: Do they want to pull the leg off?

23 MR. STOLLER: I'm not sure I mind if they pull the leg
24 off. I think he might. It's fine with us. I will have Dr.
25 McMeeking give it to them and they can pass it around.

02:48PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 THE COURT: So where are we?

2 MR. STOLLER: Question was alternative design
3 elements. One is, he identified a rounded edge of the cap as
4 fixing the issue at least on Page 62 of his report.

5 THE COURT: Anybody have a copy?

02:48PM

6 MR. STOLLER: I do. Got 80 something pages.

7 MS. HELM: The report is 25 pages.

8 MR. STOLLER: This is the March 3, 2017 report. You
9 are looking at one of the reports from the Barraza case. He
10 talks about how you can change it to make it better, sharp
11 corner --

02:49PM

12 THE COURT: Hold on. Well, he's saying a sharp corner
13 is bad.

14 MR. STOLLER: He's saying a rounded corner --

15 THE COURT: Where does it say that?

02:49PM

16 MR. STOLLER: It's this one, Your Honor. 12.
17 Possibility of a strain concentration.

18 THE COURT: All right. I see that. Do you have a
19 response to that?

20 MR. NORTH: The demonstrative we have been shown that
21 they intend to use goes far beyond those elements. And in his
22 deposition he twice disclaimed any alternative design.

02:50PM

23 THE COURT: So what -- so this is simply talking
24 about --

25 MR. STOLLER: Talking about --

02:50PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 THE COURT: Hold on.

2 MR. STOLLER: Sorry, Your Honor.

3 THE COURT: By curving or chamfering the edge or by
4 eliminating the connection to the cap. Okay. So that's in
5 there. What else do you have in the way of alternative design?
6 Well, let me ask you this. Are you going to elicit alternative
7 design testimony besides that?

02:51PM

8 MR. STOLLER: Yes.

9 THE COURT: What else are you going to elicit?

10 MR. STOLLER: Based on the examination where he was
11 examined by Ms. Daly we're going to elicit testimony that they
12 could have had caudal anchors to elicit caudal movement.

02:51PM

13 THE COURT: Where is that?

14 MR. STOLLER: Page 32. The July 6, 2017: Are there
15 any other changes you think could be made to the filters? He
16 discusses caudal anchors and penetration limiters.

02:51PM

17 THE COURT: All right. I see that on Page 32. What
18 else are you going to elicit?

19 MR. STOLLER: He also testified, Your Honor, at the
20 last trial that the two tier -- the two tier staging of the SNF
21 is a better design to alleviate tilt.

02:52PM

22 THE COURT: What is your response on those three
23 points.

24 MR. NORTH: Your Honor, I think I'm just going to --
25 I'm sorry. He says the opposite in other places. I guess I

02:52PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 just need to impeach him with that.

2 THE COURT: So the three areas are where the arms and
3 legs leave the cap; the angle while attaching to the cap,
4 caudal anchors, penetration limiters.

5 MR. STOLLER: Those are two separate things.

02:52PM

6 THE COURT: I know. And the two-staged tiered
7 approach of the Simon Nitinol. That's what you're eliciting?

8 MR. NORTH: Is the two-tiered fair game just because
9 it was mentioned in the last trial?

10 THE COURT: Well, when I said how do you feel about
11 that, you didn't state an objection.

02:53PM

12 MR. NORTH: I'm asking.

13 THE COURT: Are you asking if I would advise you to
14 object?

15 MR. NORTH: Fair enough. We would object because it
16 was not explored in either the deposition or the --

02:53PM

17 THE COURT: Is the two-tiered in the deposition or
18 report?

19 MR. STOLLER: He identified the SNF as all ulterior
20 design in his report.

02:53PM

21 THE COURT: Can you show me where?

22 MR. STOLLER: Your Honor, I will skip that one in the
23 interest of time. I know I'm not going to deal with it.

24 THE COURT: Okay.

25 (In open court.)

02:53PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 THE COURT: Thanks, Ladies and Gentlemen.

2 BY MR. STOLLER:

3 Q. Dr. McMeeking, I want to talk about some potential
4 alternative design features that you believe may have fixed
5 some of the issues you have identified. Let me talk
6 specifically about the issues you identified about the IVC
7 filter leg coming out of the cap and the concentration of
8 strains there. Do you understand what I'm talking about?

02:54PM

9 A. Yes. Yes, I do.

10 Q. What sort of design changes could Bard have made that would
11 have fixed or reduced the problems with that design issue?

02:54PM

12 A. They could have smoothed the sharp corner to make it
13 gentler.

14 Q. What effect would that have had?

15 A. That would have the effect of avoiding the severe
16 concentration of strain that can occur at that location.

02:54PM

17 Q. And in turn result in less fractures?

18 A. Correct.

19 Q. Okay. With respect to the issue of perforation, what are
20 there -- do you have opinions as to what sort of design changes
21 they could have made to either eliminate or reduce the
22 frequency of that occurrence?

02:55PM

23 A. Yes. They could have added penetration limiters which
24 would be features on the limbs that would help to slow down or
25 even stop the perforation of the limbs through the wall of the

02:55PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 IVC.

2 Q. Does that have effect on migration as well?

3 A. If designed properly, they would have helped to eliminate
4 migration down towards the feet. The hooks which are on the
5 filter already help to limit the tendency for the filter to
6 move toward your head. But adding some hook-like features that
7 would point in the opposite direction would help to stop the
8 filter going downwards.

02:55PM

9 Q. And is there a difference between a design element that you
10 would have added to alleviate the effect of movement down
11 versus the perforation?

02:56PM

12 A. Well, they could have been the same device. But in one
13 case it could have -- hook-like features would have worked. In
14 the other case of penetration limitation, somewhat blunt
15 features would help to slow down the motion of the limb through
16 the wall of the IVC.

02:56PM

17 Q. And the migration downward here, what the jury has been
18 told is called caudal?

19 A. Caudal migration.

20 Q. You would put on something called caudal anchors?

02:56PM

21 A. They are called caudal anchors.

22 Q. Where would those be placed?

23 A. They could be placed either at the feet or the hands of the
24 limbs, and they may be placed elsewhere on the limbs as is
25 convenient for the way that the device is hooked into the IVC

02:56PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 and the way that it's delivered from the delivery tube.

2 Q. Let's talk for a moment, Doctor, about your opinions with
3 respect to Bard's design processes and testing for the Eclipse
4 Filter in the prior generation. And I believe you testified
5 earlier that you have opinions with respect to Bard's actions
6 in testing its filters. What is your opinion?

02:57PM

7 A. My opinion is that the testing was inadequate.

8 Q. And why do you hold that opinion?

9 A. I hold that opinion because in some of the tests that they
10 did do the conditions that were used were not the worst-case
11 conditions that were reasonably foreseeable. And in other
12 cases, there was no test done at all. For example, there was
13 no test to look at whether the filter would tilt after it had
14 been implanted. And there was no test to look at whether the
15 limbs would have a tendency to cut through the wall of the IVC
16 and, therefore, puncture and perforate through the wall of the
17 IVC.

02:57PM

02:57PM

18 Q. Did you review Bard's bench testing?

19 A. I did.

20 Q. Did you review its finite element analysis?

02:58PM

21 A. I did.

22 Q. Was its testing reasonable?

23 A. No.

24 Q. Was its testing adequate?

25 A. No. It wasn't adequate. No.

02:58PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 Q. Why not?

2 A. Because they didn't cover all the worst-case conditions
3 that would be feasible that would be foreseeable in a
4 reasonable manner. And also, the tests, they omitted some
5 tests and calculations that they should have done to complete
6 the picture of what it was they were dealing with.

02:58PM

7 Q. Let's talk about things chronologically as they happened
8 over time.

9 You reviewed the testing and analysis they did for the
10 Recovery, correct?

02:58PM

11 A. Correct.

12 Q. Did they adequately test the Recovery to ensure that it was
13 safe for known failure modes?

14 A. No.

15 Q. What did they fail to do?

02:58PM

16 A. They failed -- as I said a moment ago, they failed to do a
17 field test. They failed to do a test that would determine
18 whether the limbs would perforate through the wall of the IVC.
19 And the fatigue test that they did was -- did not account for
20 worst-case conditions and was not run for long enough.

02:59PM

21 Q. You said the fatigue test is a bench test?

22 A. Correct.

23 Q. So they ran a bench test to see how the filter would
24 fatigue over time?

25 A. That's correct. They put a filter in a tube and then they

02:59PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 squeezed the tube, reducing its diameter by one millimeter each
2 time. And they did that for 36 million cycles of squeezing and
3 unsqueezing.

4 Q. What does that test demonstrate?

5 A. Well, it demonstrates that the filter can last 36 million
6 cycles at one millimeter of diameter change of the IVC.

02:59PM

7 Q. Was that a worst-case condition test?

8 A. No. Because it didn't account for perforation. They
9 should have pushed the limbs of the filter through the wall of
10 the tube. It didn't account for tilt, and therefore they
11 should have done a test where the filter was tilted. And they
12 should have done a test where the filter feet was, all of them,
13 were glued to the wall of the IVC to represent

03:00PM

14 endothelialization of the limbs to the IVC. And as I said,
15 they didn't run the test long enough because the objective was
16 to represent 10 years of breathing which would be about 18
17 million cycles. But instead they ran the test only for 36
18 million cycles which is about four or four and-a-half years.

03:00PM

19 Q. Well, if they run it out to 80 million cycles would it have
20 made a difference?

03:00PM

21 A. Well, in the case of the way they did the test, it would
22 not have made any difference because under the benign
23 conditions that we tested in the test, it is unlikely that it
24 would have failed even after tens or millions of cycles.

25 Q. Well, the jury saw, I believe, in openings, some guidelines

03:01PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 from the FDA about testing. And in there, the FDA talks about
2 worst-case respiratory conditions.

3 Did this test simulate worst-case respiratory
4 conditions?

5 A. No, it did not.

03:01PM

6 Q. On the spectrum from worst-case to best-case where did this
7 one fall?

8 A. I would say it was the best-case condition.

9 Q. Why?

10 A. Because of the lack of the features that I just described;
11 lack of perforation, lack of endothelialization, lack of tilt.
12 And also the size of the diameter change was relatively small
13 compared to what is understood to be possible during breathing,
14 compressing the IVC.

03:01PM

15 Q. And you reviewed the FEA that Bard performed on for the
16 Recovery, correct?

03:02PM

17 A. Yes, I did.

18 Q. Similar problems with that?

19 A. Similar problems. It lacked investigations of perforation,
20 lacked investigations of tilt, and lacked investigations of
21 endothelialization. And therefore, the calculated results were
22 not representative of worst-case conditions that could arise in
23 the IVC.

03:02PM

24 Q. Did the math or other assumptions they made other than the
25 worst-case conditions, were those the same math that you used?

03:02PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. Yes.

2 Q. And so if they had assumed some worst-case scenarios would
3 they have come to similar conclusions that you did?

4 A. Yes. If they had adopted worst-case conditions they would
5 have come to the same conclusions that I did, which is that the
6 filter is vulnerable to fatigue fracture during its useful
7 lifetime.

03:02PM

8 Q. Did Bard ever perform for the Recovery Filter a worst-case
9 scenario in testing how it would perform in the IVC?

10 A. No.

03:03PM

11 Q. Let's talk about the testing for the G2 device. And let's
12 talk for a moment about the changes Bard made when moving from
13 the Recovery to the G2.

14 What changes did Bard make to the filter in moving
15 from the Recovery to the G2?

03:03PM

16 A. They widened the base, so they moved to feet farther away
17 from each other. They lengthened the arms and they introduced
18 a more -- a smoother shape at the top where the arms come out
19 of the cap. So they made a bigger curve at the place where the
20 arms come out of the cap. And I'm sorry, they added little
21 wrist extensions on the arms.

03:03PM

22 Q. What was the effect of widening the base of the filter?

23 A. Well, it would have increased the radial force that the
24 filter would apply to the wall of the IVC because you are
25 making the spring longer, and therefore, you have to squeeze it

03:04PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 more to get it into the filter. This would have had the effect
2 of making it more firmly secured in the IVC in terms of
3 resisting migration in the towards the head, which was a
4 problem with the Recovery Filter. But it would have also
5 increased the likelihood that the limbs would cut through the
6 wall of the IVC because an increased force will tend to have
7 that effect.

03:04PM

8 Q. Did it also have an effect on the issue of tilt as you
9 earlier described?

10 A. Yes. The widening the stance would have made tilt a more
11 severe problem for the same reason that it's longer spring
12 which wants to get back to its length and has more strain,
13 stress, and energy stored in it. But it will make it want to
14 do so.

03:04PM

15 Q. Similar same effect on migration?

03:05PM

16 A. Yes. Because the tilt can contribute to caudal migration.
17 It would have had a similar impact on caudal migration.

18 Q. Why would the filter go down rather than up?

19 A. Well, the hooks that help to secure it into the wall of the
20 IVC are oriented so that they are designed to stop the filter
21 moving upwards. They are oriented hooks like this. But they
22 have little effect on the filter being pushed downwards where
23 the hooks can become disengaged from the wall of the IVC.

03:05PM

24 Q. Why did Bard make that change? Why did it widen the base
25 of the IVC filter?

03:05PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. Because they were having trouble with migration, movement
2 of the filter towards the head.

3 Q. In your analysis of Bard's design process, did they
4 determine why the Recovery Filter was migrating up?

5 A. They never did a complete root cause analysis of the
6 failure of the filter, so they never were sure of exactly what
7 was causing the various effects that they were identifying as
8 failure of the Recovery Filter.

03:06PM

9 Q. Is that a problem?

10 A. Yes.

03:06PM

11 Q. Why?

12 A. Because to make design changes that would be appropriate
13 and would make sure that they address the problems, they should
14 first know what was causing the problems. And it is also
15 guiding principle of engineering design that if there are
16 failures occurring that one should identify what is causing
17 those failures so that one can reduce them to the extent
18 feasible.

03:06PM

19 Q. Did Bard test and analyze other of the failure modes and
20 complications that the Recovery was experiencing in making its
21 design changes to the G2 Filter?

03:07PM

22 A. In the G2 Filter, which was the modified one, they did not
23 test for all of the failure modes which were foreseeable in the
24 G2.

25 Q. What tests should they have conducted?

03:07PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. They should have conducted a test to see whether the filter
2 would tilt. They should have conducted a test to see whether
3 the filter would -- whether the limbs would perforate the wall
4 of the IVC, and they did not perform -- they should have
5 carried out a respiratory fatigue test type that I just
6 described where you take the filter and you expand and contract
7 the tube by an appropriate amount to test how long it will last
8 before fatigue failure occurs over a 10-year breathing life
9 span.

03:07PM

10 Q. I think you testified they did one of those for the
11 Recovery, correct?

03:08PM

12 A. They did one for the Recovery although it was not adequate
13 because it was not long enough, but they did such a test for
14 the Recovery.

15 Q. Is it reasonable for Bard to rely on the fatigue test you
16 described for the Recovery as basis for finding that the G2
17 Filter was reasonably and adequately designed?

03:08PM

18 A. No, it was not.

19 Q. Why not?

20 A. Because they had not carried out -- had not succeeded in
21 carrying out a root cause analysis of why the fractures were
22 taking place, and therefore, they were not sure of what design
23 changes would actually address the likelihood or the tendency
24 for fatigue fracture to occur.

03:08PM

25 Q. Did Bard run a finite element analysis to analyze that

03:08PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 issue?

2 A. They tried to. They carried out finite element analysis
3 which they then misinterpreted and wrongly used to justify
4 omitting a respiratory fatigue test of the filter, of the G2
5 Filter.

03:09PM

6 Q. And when you say they wrongly used, what was wrong with
7 those FEAs?

8 A. Well, the calculation that they did was to take the filter,
9 put it into the delivery tube, and then expand it into an IVC.

10 And they took that as information that they could use to

03:09PM

11 justify an improved fatigue performance of the filter.

12 However, all that does is determine what the -- all that

13 calculation did was determine what the strains were when the

14 filters were introduced into the IVC. It did not determine

15 what the strain changes were, the loading and unloading that

03:09PM

16 the filter would experience once breathing commenced and it was
17 squeezed and unsqueezed over and over again.

18 Q. So the FEA only looked at the filter coming out of the tube
19 and being placed?

20 A. Correct.

03:10PM

21 Q. Not the lifetime of the filter?

22 A. That's correct.

23 Q. Any examination of worst-case foreseeable conditions in the
24 IVC?

25 A. No. The calculations that they did were not addressing

03:10PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 worst-case fatigue conditions that would be foreseeable within
2 the IVC.

3 Q. They did conduct a fatigue test, did they not?

4 A. Yes, they did.

5 Q. What was that?

03:10PM

6 A. It is one that is referred to as the saluting arm fatigue
7 test.

8 Q. And what is that test?

9 A. Well, what they did was they took the filter and they cut
10 its legs off and then they took the arms and --

03:10PM

11 MR. STOLLER: Before you go on, Your Honor, could we
12 turn on the ELMO so that the jury could see?

13 THE COURT: Yes.

14 MR. STOLLER: Thank you.

15 THE WITNESS: So they took the G2 Filter and they cut
16 its legs off, and then they held it by the cap in the way that
17 I'm doing and then they pushed a tube up to push the arms up
18 and down. And so if you now look at me, you can see the effect
19 of the tube being pushed up and down was to cause the arms to
20 go up and down like this, so what was -- to cause the arms to
21 go up and down like this, and they did that several times on
22 both the Recovery and the G2 Filter until the arms broke.

03:10PM

03:11PM

23 BY MR. STOLLER:

24 Q. So in other words, they flapped the arms up and down like
25 this?

03:11PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. Yes. They flapped the arms up and down like this, like an
2 umbrella that was going inside and outside as the deformation
3 took place.

4 Q. So what does that test, as somebody who has been a
5 mechanical engineer and a materials engineer and a professor on
6 those subjects for 45 years, what does that test tell you about
7 those devices?

03:11PM

8 A. Well, it tells you that if you move the arms up and down by
9 the distance you move them it would last a number of cycles
10 that the filter lasted, but it would not give you a general
11 assessment of the fatigue durability of the filter. It would
12 only be information about that one particular failure mode if
13 that failure mode is one that was is foreseeable.

03:12PM

14 MR. STOLLER: Gay, would you pull up Exhibit 876,
15 please?

03:12PM

16 BY MR. STOLLER:

17 Q. Doctor, are you familiar with this document?

18 A. Yes.

19 MR. STOLLER: Your Honor, I would move into evidence
20 Exhibit 876.

03:12PM

21 MR. NORTH: No objection, Your Honor.

22 THE COURT: Admitted.

23 MR. STOLLER: Gay, would you go to Page 9397. Thank
24 you.

25 Your Honor, may be publish this to the jury?

03:12PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 THE COURT: Yes.

2 MR. STOLLER: Thank you.

3 BY MR. STOLLER:

4 Q. Doctor, I believe the jury has seen this chart before in
5 opening statement. What does this chart show? 03:13PM

6 A. This chart summarizes the results of the saluting arm
7 fatigue test on the current -- on the Recovery which is on the
8 left, the purple box, and the, what is now the G2 called the
9 modified RF on the right-hand side, and what it shows is that
10 in the saluting arm test the Recovery Filter arms lasted on 03:13PM
11 average 57 motions up and down whereas the G2 Filter had its
12 arms last for an average of 628 movements up and down.

13 Q. Are you familiar with Bard's claim that the G2 Filter was
14 12 times more fracture resistant than the Recovery?

15 A. Yes, I am. 03:14PM

16 Q. Is this test the basis for that claim?

17 A. It is except the data that you are seeing actually is --
18 shows that it's 11 times better. But there are other data
19 which are slightly different from these which have a factor of
20 12 as the length of -- number of cycles that the G2 lasted 03:14PM
21 compared to the Recovery. So in that sense this is the backing
22 for the claim that the filter is 12 times more fatigue
23 resistant -- the G2 is 12 times more fatigue resistant than the
24 Recovery.

25 Q. Whether it's 11 or 12 times, what does this tell you? What 03:14PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 do these results tell you in terms of general fracture
2 resistance?

3 A. Nothing.

4 Q. Why not?

5 A. Because it addresses only one particular failure mode which
6 may be significant but does not give you insights into the more
7 general performance of the filter in terms of how it would last
8 for millions and millions of cycles of breathing.

03:14PM

9 Q. You have seen Bard's internal documents. Did they expect
10 that the Recovery -- I'm sorry -- that the G2 Filter was going
11 to experience the saluting arm problem?

03:15PM

12 A. Well, no. They had some indication that the recovery was
13 experiencing that kind of problem when the arms got trapped in
14 renal veins and so on. But they expected the lengthening of
15 the arms would help to eliminate that problem.

03:15PM

16 Q. Was that a problem with the G2 Filter?

17 A. You mean the arms being --

18 Q. Saluting arm?

19 A. The arm being trapped in the renal vein is a problem?

20 Q. With the G2?

03:15PM

21 A. With the G2, not to my knowledge.

22 Q. Are there tests that can be done to improve general
23 fracture resistance?

24 A. Yes.

25 Q. Have you already testified about those?

03:15PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. I have. It's the respiratory fatigue test in worst-case
2 conditions that would tell you that sort of information.

3 Q. Based on your experience would it be accurate in any
4 circumstance to say that this test proves that the G2 is 12,
5 11, even 10 times more fracture resistant than the Recovery? 03:16PM

6 A. No. It would be completely unreasonable to use this
7 information to make such a claim.

8 Q. And did Bard ever conduct any tests to demonstrate that the
9 G2 was more fracture resistant than the recovery?

10 A. Not to my knowledge. 03:16PM

11 Q. Let's talk next about the changes that they made to the
12 G2X. Are you familiar with those?

13 A. I am, yes.

14 MR. STOLLER: Your Honor, can we use the ELMO again so
15 Dr. McMeeking can display the filter to the jury? 03:16PM

16 THE COURT: Yes.

17 BY MR. STOLLER:

18 Q. Would you tell the jury what changes were made to the G2X?

19 A. Well, the G2X was simply the G2 with the hook where my
20 finger is, the hook at the top added on to the cap with some 03:17PM
21 detail changes to the shape of the cap. But otherwise it was
22 identical to the G2.

23 Q. At the time that Bard had put out the G2X or was designing
24 and putting out the G2X, what complications was the G2 Filter
25 experiencing? 03:17PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. In terms of why they added the hook?

2 Q. No. I'm asking what complications it was experiencing
3 without regard to the design.

4 A. So it was experiencing fractures. It was experiencing
5 caudal migration. It was experiencing tilt. And it was
6 experiencing perforation.

03:17PM

7 Q. So the four things you have testified about already today,
8 correct?

9 A. Yes. Correct.

10 Q. What of those issues does this design change have any
11 effect on?

03:17PM

12 A. None of them.

13 Q. Let's talk about what happened when they changed from the
14 G2X to the Eclipse. What design changes were made there?

15 A. The Eclipse is the G2 Express electropolished. So they
16 polished the surface of the metal by an electropolishing
17 methodology.

03:18PM

18 Q. Any other changes?

19 A. Well, it became blue.

20 Q. And we talked about the fact that the G2 was experiencing
21 fracture, tilt, migration and perforation?

03:18PM

22 A. Correct.

23 Q. Did this design change have any effect on tilt?

24 A. No.

25 Q. Did it have any effect on migration?

03:18PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. No.

2 Q. Did it have any effect on perforation?

3 A. No.

4 Q. Did it have any effect, under your analysis, on fracture?

5 A. It did not have a meaningful effect on fatigue fracture.

03:18PM

6 Q. Why not?

7 A. Because the improvement of the fatigue properties was so

8 small and marginal that it was not enough to deal with the

9 severe conditions that the filter would experience in its

10 worst-case situation.

03:19PM

11 Q. In your analysis and review of Bard's actions in designing
12 and testing the Eclipse Filter, did they conduct adequate root
13 cause analysis to determine why the complications were
14 happening with the G2 Filter?

15 A. No. They never carried out a root cause analysis that told
16 them why the recovery was suffering failures, why the G2 was
17 suffering failures, why the G2 Express was suffering failures.

03:19PM

18 Q. Did they conduct tests to determine whether any of these
19 changes would correct any of those failures?

20 A. No. To my knowledge, they conducted no tests that
21 addressed whether these changes would address the problems the
22 filters were having.

03:19PM

23 Q. The calculations that you have done here, the FEA analysis
24 that you did using the computer program, how difficult are
25 those to conduct?

03:19PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 A. They are quite straightforward. We teach third and fourth
2 year students to do such calculations during their classes on
3 analysis and design.

4 Q. Is Bard's failure to conduct root cause analysis as to the
5 complications that were being experienced by the Recovery and
6 then by the G2 reasonable?

03:20PM

7 A. No.

8 Q. Is its failure to test to see if its filters adequately
9 addressed those issues and minimized the complications
10 reasonable?

03:20PM

11 A. No.

12 Q. Are there any differences, materially, in terms of the
13 problems that that the filters are experiencing between the G2
14 Filter and the Eclipse Filter that was implanted in Mrs. Jones?

15 A. There's no difference.

03:20PM

16 Q. Doctor, I have asked you a lot of questions today. Are the
17 opinions that you have expressed here today held to a
18 reasonable degree of engineering and scientific probability?

19 A. Yes, they are.

20 Q. And are the methods that you have used in making your
21 determinations and coming to your opinions accepted as standard
22 in the areas of mechanical engineering and materials
23 engineering?

03:21PM

24 A. Yes, they are.

25 MR. STOLLER: Thank you, Your Honor. I have no

03:21PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Direct

1 further questions at this time.

2 THE COURT: Cross-examination?

3 MR. NORTH: Yes, Your Honor.

4 THE COURT: Before we start for a minute, we talked at

5 sidebar about the possibility of the jury holding the filter. 03:21PM

6 Why don't we do that before the cross-examination?

7 MR. NORTH: Okay.

8 MR. STOLLER: Do you mind, Dr. McMeeking?

9 THE WITNESS: No. I don't mind at all.

10 MR. STOLLER: May I approach? 03:21PM

11 THE COURT: You may.

12 If you want to stand up, Ladies and Gentlemen, while

13 we do this feel free.

14 Mr. North, your cross-examination.

15 MR. NORTH: Thank you, Your Honor. 03:25PM

16 CROSS-EXAMINATION

17 BY MR. NORTH:

18 Q. Good afternoon, Dr. McMeeking.

19 A. Good afternoon.

20 Q. You and I have met before, haven't we? 03:25PM

21 A. Yes, we have.

22 Q. And you told us earlier that you charge \$400 an hour for

23 your work in reviewing materials and \$800 an hour for

24 testifying. Correct?

25 A. That's correct. 03:25PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 Q. And that's whether you are testifying by deposition or in a
2 courtroom?

3 A. That's correct.

4 Q. And you have been working with this group of attorneys
5 representing Ms. Jones for a number of years, correct?

03:25PM

6 A. Yes, I have.

7 Q. And over the course of those years they have paid you tens
8 of thousands of dollars for your work, correct?

9 A. That's correct.

10 Q. And you told us earlier that you also are working in
11 litigation against another filter manufacturer, Cook Medical,
12 correct?

03:25PM

13 A. That's correct.

14 Q. And you are working for the same group of attorneys in that
15 proceeding as you are in this proceeding, correct?

03:26PM

16 A. Well, I don't see any attorneys in the courtroom today that
17 I am working with in the Cook litigation.

18 Q. But you are aware that some of the attorneys involved in
19 this litigation against Bard are also involved in the
20 litigation against Cook, correct?

03:26PM

21 A. I'm not aware of the relationship among all of the
22 attorneys.

23 Q. And you have been paid tens of thousands of dollars by the
24 attorneys in the Cook litigation, correct?

25 A. That's correct.

03:26PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 Q. And, in fact, you testified in a trial last October in
2 Evansville, Indiana, against Cook regarding an IVC filter,
3 correct?

4 A. That's correct.

5 Q. And in that trial, you testified also that you believe the
6 Cook filter was defective in its design, correct?

03:26PM

7 A. That's correct.

8 Q. And in that litigation, you have also criticized the
9 testing that Cook Medical performed on its filter, correct?

10 A. That's correct.

03:27PM

11 Q. And as a part of that criticism, you have said that Cook
12 failed to conduct adequate fatigue testing of its filter?

13 A. That's correct.

14 Q. And you have, like you did here a few minutes ago, you have
15 said in that litigation that Cook failed to conduct worst-case
16 scenario testing just like you fault Bard for, correct?

03:27PM

17 A. That is correct.

18 Q. And did you testify yesterday against Cook?

19 A. No. I did a deposition about in February which I believe
20 they are using in video form at the Cook trial that's going on
21 right now.

03:27PM

22 Q. So are you aware that a videotape deposition of you
23 criticizing the Cook filters was played in a courtroom in
24 Houston, Texas yesterday?

25 A. I am not sure if that was the case, but I am aware of the

03:27PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 fact they were planning to show it.

2 Q. Dr. McMeeking, you have not written any publications
3 specifically on IVC filters, have you?

4 A. No, I have not.

5 Q. And the few publications that you have written that
6 specifically mention medical devices concern heart valves, is
7 that correct?

03:28PM

8 A. That's correct.

9 Q. And you, yourself, have never designed a medical device?

10 A. No, I have not.

03:28PM

11 Q. And obviously, then, you have never designed an inferior
12 vena cava filter?

13 A. That's correct.

14 Q. And independent of your work as a retained or hired expert
15 witness in this litigation, you have never before performed an
16 analysis of an IVC filter, have you?

03:28PM

17 A. That's correct.

18 Q. And other than your work as a paid expert in this
19 litigation, you have never been involved in any testing of an
20 IVC filter, have you?

03:28PM

21 A. That's correct.

22 Q. And, of course, you have never conducted or been involved
23 in any clinical study of an IVC filter?

24 A. No, I have not.

25 Q. And you are not a biomedical engineer, correct?

03:29PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 A. I am not a biomedical engineer. I'm a mechanical engineer
2 with significant interests in biomedical engineering.

3 Q. Now, you are not a medical doctor, obviously?

4 A. I am not.

5 Q. And you are not an expert on when and in which patients an
6 IVC filter should be used?

03:29PM

7 A. No, I'm not.

8 Q. And you have never placed or retrieved an IVC filter,
9 obviously?

10 A. No, I have not.

03:29PM

11 Q. Now, in this litigation, Dr. McMeeking, as you have told us
12 earlier, you are not offering any opinions that Bard's filters
13 had higher rates of any particular type of complication
14 relative to other manufacturers' filters, are you?

15 A. I have not made that assessment so I am not offering such
16 opinions.

03:29PM

17 Q. And you have similarly not made any assessment as to
18 whether one type of Bard filter has a higher rate of
19 complication than another type of Bard filter, have you?

20 A. No. I have not made that assessment.

03:30PM

21 Q. And you are aware of the fact that there have been
22 complications including perforation, tilt, fracture, and
23 migration in IVC filters generally, correct?

24 A. Yes. They are common problems in IVC filters.

25 Q. And you have seen those common problems in IVC filters with

03:30PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 the Cook filters you have assessed, correct?

2 A. That's true.

3 Q. Let's talk about your testing for a minute. My
4 understanding is that you performed two FEAs, or finite element
5 analyses, correct?

03:31PM

6 A. I think I may have done three sets of analyses. I haven't
7 counted them specifically.

8 Q. The first one you did concerned arm strain on a Recovery
9 Filter. Is that correct?

10 A. That's correct.

03:31PM

11 Q. And let's -- the second one concerned tilting with the G2
12 Filter, correct?

13 A. That's correct.

14 Q. And what did the third one concern?

15 A. Well, it's further tilting calculations, so I'm just
16 counting them as separate types of tilting calculations.

03:31PM

17 Q. So that we're clear, because I want to talk about each of
18 these individually, your first finite element analysis
19 concerned arm strain in the Recovery Filter?

20 A. Correct.

03:31PM

21 Q. Your other two finite element analyses concerned tilting
22 with a G2 Filter, correct?

23 A. That's true, but I should clarify what I said about the
24 Recovery arm calculation. I did finite element calculations

25 that represent both the Recovery Filter and the G2. So I did

03:32PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 finite element calculations for the arms of both the Recovery
2 and the G2.

3 Q. Okay. So but in these three finite element analyses, none
4 of them specifically concerned the Eclipse Filter, did they?

5 A. Not directly, but the Eclipse Filter is mechanically and
6 materially the same as the G2, and therefore, the calculations
7 for the G2 were also calculations for the Eclipse.

03:32PM

8 Q. Did you perform any finite element analyses of the G2X?

9 A. No. But the G2X is materially and mechanically the same as
10 the G2 except for the hook. And therefore, the calculations I
11 carried out for the G2 are also calculations that are valid for
12 the G2X.

03:32PM

13 Q. Didn't you tell us just a few moments ago that the G2X had
14 some modifications made to the cap as well as the hook?

15 A. They are small changes to the outside shape of the cap.

03:33PM

16 Q. Well, regardless whether they are small changes or large
17 changes, the fact of the matter is, you did not perform a
18 finite element analysis specifically on a G2X Filter, correct?

19 A. It was not a geometry of the cap that was exactly that of
20 the G2X. But otherwise relevant portions of the calculations
21 were the same.

03:33PM

22 Q. That wasn't my question. My question was very simple.

23 Whether you believe the test you performed on the G2 has
24 application to another filter or not, did you specifically
25 perform finite element analysis on a G2X Filter?

03:33PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 A. I'm going to revise my answer in the following sense, that
2 the cap was not part of the model that was used because it was
3 not necessary to include the cap in the calculation. So the
4 calculation could equally well have been for the G2X as it was
5 for the G2.

03:34PM

6 Q. And you have admitted earlier, I believe, that the
7 electropolishing performed on the Eclipse Filter could have at
8 least some impact on the fracture resistance of that device,
9 correct?

10 A. Yes, it would have improved the fracture resistance to some
11 extent.

03:34PM

12 Q. And yet you have not performed a finite element analysis
13 specifically on an Eclipse Filter to assess arm strength,
14 correct?

15 A. I carried out the calculation for the G2 arm shape which
16 did not include the cap or was not -- it was not affected by
17 the question of what the surface polishing was. So that
18 calculation for the G2 is equally valid for the Eclipse.

03:34PM

19 Q. Let's talk about these finite element analyses you did for
20 the arm strength. My understanding is that you calculated on
21 only one arm the strain, is that correct?

03:35PM

22 A. That's correct, one arm is representative of all six.

23 Q. And you did not analyze as a part of this finite element
24 analysis the arm -- or the leg strength on any of the legs,
25 correct?

03:35PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 A. I did not analyze the leg strain in my calculations.

2 Q. And as I understand it, as you said earlier, you had to
3 make a number of assumptions to do this finite element
4 analysis, right?

5 A. That's correct.

03:35PM

6 Q. Because you are putting these assumptions into the computer
7 to run this program, correct?

8 A. That's correct.

9 Q. And you have heard the term garbage in, garbage out, right?

10 A. I'm aware of that expression, yes.

03:35PM

11 Q. And that basically means if you don't put the right data in
12 or the right assumptions in you are not going to get valid
13 responses out, correct?

14 A. That's what it means, but I did not put garbage in and I
15 did not get garbage out.

03:36PM

16 Q. I'm just asking if you know of the concept.

17 A. I know of the concept.

18 Q. Now, when you were making these assumptions using only one
19 arm, you assumed that that one arm was perforating the inferior
20 vena cava, correct?

03:36PM

21 A. No. That's not completely true. In some of the
22 calculations I did, the arms were not perforating the vena
23 cava. In other calculations I did, the arm was indeed
24 perforating the vena cava. And because of symmetry conditions,
25 that one arm was representative of all six and would behave in

03:36PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 the way that it would given the presence of all six arms.

2 Q. Well in at least some of your calculations, you assume that
3 that one arm was perforated almost halfway through the inferior
4 vena cava, correct?

5 A. That's correct, because that would be the worst-case
6 condition that could arise.

03:37PM

7 Q. And my understanding is that this finite element analysis
8 that you conducted on the arm strength of the Recovery -- and
9 did you do the same test for the G2?

10 A. Sir, could you ask the question again?

03:37PM

11 Q. Did you do the same arm strain test for the G2 that you did
12 for the Recovery?

13 A. I did calculations for the Recovery and the G2 for arm
14 strain in the manner that you have just described.

15 Q. And for the G2 also, some of the tests had the -- you
16 assumed the arm was perforating the inferior vena cava by up to
17 half of the length of the arm?

03:37PM

18 A. Yes. Some calculations were done with that extent of
19 perforation; others were done with less perforation and others
20 were done with no perforation.

03:37PM

21 Q. And my understanding, as you have told us before, is that
22 your test in this finite element analysis showed that in some
23 scenarios, the failure -- I mean the fracture -- I'm sorry, the
24 filter would fail within seven to 10 respiratory cycles. Is
25 that correct?

03:38PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 A. That would only happen after the processes that lead to
2 perforation and endothelialization of the filter had taken
3 place, and that could be a matter of months or years. And so
4 the short span of breathing would be only causing the filter to
5 fail after that process had occurred and the worst-case
6 conditions had arisen. 03:38PM

7 Q. So but what happened is when you put it in the worst-case
8 scenario, made that assumption for the finite element analysis,
9 that had the arm perforating the IVC by halfway. In that
10 worst-case scenario, the arm was failing within 7 to 10
11 respiratory cycles, correct? 03:39PM

12 A. That would be the case, yes.

13 Q. And when we say, of course, 7 to 10 respiratory cycles
14 that's 7 to 10 human breaths, correct?

15 A. That's correct. 03:39PM

16 Q. And if that was happening out there in the field with
17 filters, most people would be having a fractured filter before
18 they even got off the procedure table, wouldn't they?

19 A. No, that's not true because the procedure puts in a filter
20 which is entirely inside the vena cava, and it takes time for
21 the vena cava -- for the filter to cut through the wall of the
22 vena cava and get into the condition that you are describing.
23 And that period of time could be months or years.

24 Q. Your testing demonstrated that the worst-case scenario or
25 highest stresses on these filters would occur when there was 03:39PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 perforation, correct?

2 A. That's correct.

3 Q. Are you aware of the fact, Dr. McMeeking, that there has
4 been no medical evidence that the filter implanted in Ms. Jones
5 ever perforated the inferior vena cava?

03:40PM

6 A. I have seen no reports of perforation. That's correct.

7 Q. And, in fact, in the report that you gave in this case, you
8 noted the fracture and other things, but you noted no
9 perforation, correct?

10 A. That's correct.

03:40PM

11 Q. And you did claim that there was a tilt with Ms. Jones'
12 filter, correct?

13 A. That's correct.

14 Q. Are you aware of how great or significant the tilt was?

15 A. No. I'm only aware of the fact that it was tilted.

03:40PM

16 Q. Are you aware of the fact that the estimate of another
17 expert by the plaintiff is that the tilt was only four degrees?

18 A. I'm not aware of that assessment.

19 Q. Would you agree that a four-degree tilt is a very slight
20 tilt?

03:40PM

21 A. That is a slight tilt, yes.

22 Q. And your report mentions something about this filter
23 migrating in the caudal or downward position, the filter
24 implanted in Ms. Jones, correct?

25 A. That's correct.

03:41PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 Q. But you don't have any independent knowledge of that?

2 A. No. I'm relying on Doctors Hurst and Muehrcke for that
3 information.

4 Q. So you are relying on other experts for that?

5 A. Correct.

03:41PM

6 Q. In the testing you did with the G2 Filter regarding tilt,
7 did any of that testing involve tilt with a magnitude, or as
8 small as four degrees?

9 A. Well, my calculations involved such small amounts of tilt
10 because the process of tilt starts at zero and grows
11 progressively. So in that sense, yes, it involved -- some of
12 the calculations involved small amounts of tilt of the amount
13 that you are describing.

03:41PM

14 Q. Now, in the finite element analyses that you were
15 performing, you assumed that when the arm had perforated or
16 penetrated the wall of the IVC that it had, in fact,
17 endothelialized and therefore was rigid and could not move,
18 correct?

03:42PM

19 A. Well, it was not rigid but it was held firmly so it cannot
20 rotate at the wall. So that was the outcome of the assessment
21 of endothelialization that I used.

03:42PM

22 Q. But it was firmly entrenched so it could not move at that
23 point?

24 A. It was firmly entrenched so over short-term cycles of
25 breathing it would not move.

03:42PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 Q. You have not made any assessment or don't have any basis to
2 make a determination as to how often a filter arm perforates
3 the inferior vena cava to the extent that you tested for as
4 your worst-case scenario, do you?

5 A. No, I have not.

03:43PM

6 Q. So you don't know if that happens 10 percent of the time or
7 .0010 percent of the time?

8 A. No, I do not know.

9 Q. In your testing, you also assumed that the movement of the
10 inferior vena cava, the vein itself, was not affected or
11 impacted by the presence of the filter. Correct?

03:43PM

12 A. That's correct.

13 Q. Now, you, as I understand it, did this computer modeling
14 and you did this -- some mathematical calculations, correct?

15 A. Correct.

03:44PM

16 Q. You did not do any bench testing of a Bard filter, did you?

17 A. No, I did not.

18 Q. You did not do any animal testing of a Bard filter, did
19 you?

20 A. No, I did not.

03:44PM

21 Q. I think you said this, but I want to make certain. Under
22 your finite element analysis calculations, the less perforation
23 there was, the less strain there was on the arm, correct?

24 A. That's correct, for the same amount of motion of the wall
25 of the vena cava.

03:44PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 Q. For those tests you performed where there was no
2 perforation, there was less strain on the arm than if it was
3 significantly perforated, correct?

4 A. Correct, for the same motion of the vena cava wall.

5 Q. And if you had assumed as a part of your calculations that
6 the arm was not immobilized by endothelialization, the stresses
7 would have been less in your calculations, correct?

03:45PM

8 A. That's correct.

9 Q. And the reason you made all these assumptions was your
10 effort to test for the worst-case scenario, correct?

03:45PM

11 A. That's correct.

12 Q. But you have no way of knowing with what frequency this
13 worst-case scenario actually occurs in patients, do you?

14 A. No, I do not have that assessment.

15 Q. You would agree with me that there may are likely patient
16 specific conditions that contribute to events like tilt or
17 fracture in a filter, correct?

03:45PM

18 A. Well, the anatomy and the physiology is very variable so
19 different patients would have different effects on their
20 filters.

03:46PM

21 Q. You would agree with me that a manufacturer should not be
22 expected to design a product to withstand all worst-case
23 scenarios, correct?

24 A. I agree, yes.

25 Q. Because if you develop a product to withstand all

03:46PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 worst-case scenarios, you may eliminate the ability of that
2 product to provide certain benefits, correct?

3 A. It could eliminate benefits, that's correct.

4 Q. And therefore, you agree that the risks associated with any
5 implantable device such as an IVC filter cannot be zero?

03:46PM

6 A. I'm not sure if that's the case, but it's unlikely that the
7 risks could be zero.

8 Q. Now, you have done no testing to try to quantify the extent
9 of the improvement of the fracture resistance of the filter by
10 electropolishing it to produce the Eclipse, correct?

03:47PM

11 A. Well I did calculations and then compared the results of
12 the calculations with the improvement in the fatigue
13 properties.

14 Q. So you did some calculations that made assumptions based on
15 electropolishing?

03:47PM

16 A. Yes. I took data from Bard which assessed the improvement
17 in the fatigue limit, and I compared the improvement of the
18 fatigue limit with the results from my calculations.

19 Q. But you did not do any independent assessment as to what
20 the extent of that improvement was, correct?

03:47PM

21 A. I'm not sure what you -- can you -- I don't understand your
22 comment "independent." I'm sorry.

23 Q. You just said you used Bard's data and then plugged that
24 into your calculations, correct?

25 A. Correct. I didn't measure the fatigue limit of the

03:48PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 electropolish Nitinol myself.

2 Q. And again, you did no bench testing with an Eclipse Filter
3 that would help you assess the fatigue limits of that device?

4 A. That's correct.

5 Q. Have you made any analysis as to what degree of tilt in
6 your view will lead to perforation or fracture?

03:48PM

7 A. I have not made any assessment directly of that nature.

8 Q. Doctor, earlier in response to some questions from Mr.
9 Stoller, you mentioned several things that you thought could be
10 done to the Bard filters to improve their design, correct?

03:49PM

11 A. Correct.

12 Q. If we bring up -- do you have his deposition from July 6 of
13 2017? July 6 of 2017. We'll get to that later.

14 You have it? Okay. If we could pull up Page 36.

15 If we could look at Page 36, Line 10. And do you
16 recall this deposition on July 6 of 2017 where my partner, Ms.
17 Taylor Daly, took your deposition?

03:50PM

18 A. Yes, I do.

19 Q. And at that time, you were asked the following: "All
20 right. So we'll set that aside for a moment. But you -- you
21 have developed no prototype making changes to any of Bard's
22 filters that you think would perform better, correct?"

03:50PM

23 A. That's correct.

24 Q. And your answer to that question was: "No. I have -- I
25 have developed no prototype to attempt to achieve that

03:50PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 objective, correct?"

2 A. That's correct.

3 Q. And that is correct today, right?

4 A. That's correct today, yes.

5 Q. You are offering some ideas that you think might help, but 03:51PM

6 you have not developed an alternative design and you have not

7 tested an alternative design, correct?

8 A. That's correct.

9 Q. You have not run finite element analyses on an alternative

10 design? 03:51PM

11 A. That's correct.

12 Q. And you have not done mathematical calculations on an

13 alternative design?

14 A. No, I have not.

15 Q. And if we could turn in the same deposition to Page 150. 03:51PM

16 Looking at Line 4. At that time point you were asked in this

17 deposition a year ago less, than a year ago, July 6 of 2017:

18 "Do you know of modifications to the Bard filters, any of them,

19 that would have made them unable to fracture, tilt, perforate,

20 or migrate?" 03:51PM

21 And your answer was: "I haven't studied that."

22 Correct?

23 A. Correct.

24 Q. So while you have mentioned several things in response to

25 Mr. Stoller, the fact of the matter is, you have not made an 03:52PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 engineering or scientific study or assessment to come up with
2 an alternative design that would eliminate the complications
3 you are talking about here today?

4 A. I have not, but I would draw your attention to the fact
5 that the question says unable to fracture tilt, perforate, or
6 migrate. And my assessments have been to look at what would
7 reduce the extent of fracture, tilt, perforate, or migrate.

03:52PM

8 Q. But as you told -- we looked at that earlier question and
9 answer where you admitted that you have developed no prototype
10 making changes that would perform better, correct?

03:52PM

11 A. That's correct.

12 Q. You recognize, Doctor, that many companies electropolish
13 Nitinol products in this day and age, correct?

14 A. That's correct.

15 Q. And in doing so, they do so, I believe you have told us,
16 because it's considered a way of improving the fatigue
17 performance of the material?

03:53PM

18 A. That's correct.

19 Q. And, in fact, that's what you have determined occurred
20 here. The Eclipse did improve the fatigue performance of the
21 G2 Filter, correct?

03:53PM

22 A. I don't believe I made that direct comparison. What I said
23 was that the electropolishing was shown to increase the fatigue
24 limit and that would have had an effect on the fatigue life of
25 the filter.

03:53PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 Q. Have you done any calculations as to what would cause the
2 fracture of a filter that did not perforate?

3 A. Yes, because I have looked at Valsalva and phenomena like
4 that.

5 Q. Did any of your calculations show that a tilt as minimal as
6 four degrees could have an impact on the fatigue resistance?

03:54PM

7 A. Well, it would have had some effect but not a big effect.

8 Q. And it could have been a very minor effect if one at all,
9 correct?

10 A. Correct.

03:54PM

11 Q. And you certainly are not able to say that a four degree
12 tilt would put a sufficient force of strain on an arm to result
13 in a fracture, correct?

14 A. Can you ask the question again please?

15 Q. You are not able to say that a tilt as minor or minimal as
16 four degrees could put sufficient strain on an arm to cause a
17 fracture, can you?

03:55PM

18 A. It would be the combination of a four degree tilt and
19 whatever was happening to the IVC. So I don't know if that
20 could be the outcome of the calculation or not.

03:55PM

21 Q. So you don't know whether that could result in a fracture
22 or not at this point, just a four-degree tilt?

23 A. Well, if the compression of the vena cava was big enough
24 and there was enough of them, the four-degree tilt might put it
25 over the critical level that would cause it to begin to have

03:55PM

~~5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross~~

1 fatigue problems. That's a possibility.

2 Q. But you didn't do calculations or finite element analyses
3 that would demonstrate that, correct?

4 A. No. That's correct. I did not.

5 Q. You have come into court this afternoon and you have talked 03:56PM
6 about your calculations and your computer modeling. And you
7 have not brought any specific calculations or presented them to
8 this jury, have you?

9 A. No, I have not.

10 Q. And you have not presented this jury with any test reports 03:56PM
11 like the Bard test reports that you reviewed, correct?

12 A. That's correct, yes.

13 Q. And while you had a lot of criticisms about the Bard test
14 reports you have admitted to us that you personally have never
15 conducted bench testing like that on any medical device, 03:56PM
16 correct?

17 A. That's correct.

18 Q. Thank you, sir. That's all I have.

19 THE COURT: Redirect?

20 REDIRECT EXAMINATION 03:56PM

21 BY MR. STOLLER:

22 Q. Dr. McMeeking, you were just asked if you have ever
23 conducted bench testing on a medical device. Why not?

24 A. Because I do calculations and I do theory. I'm not an
25 experimentalist so I don't have a lab and, therefore, I don't 03:57PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Cross

1 do bench tests myself.

2 Q. You were asked whether you had presented the mathematical
3 calculations that you performed to this jury.

4 Have you presented them to the defendants in this
5 case?

03:57PM

6 A. Yes, I have.

7 Q. Where were they?

8 A. They were in my report.

9 Q. Have you given them your FEA analysis that you did?

10 A. I recall that we gave them some input files for FEA.

03:57PM

11 Q. Okay. Is the math that you performed here something that's
12 not capable of being done by engineering students?

13 A. No. Some of the calculations I did could be done by
14 second-year students. In fact, we teach second-year students
15 those kind of calculations and others are more complicated. So
16 maybe a third- or a fourth-year student or a graduate student.

03:58PM

17 Q. Is the math you did similar to the analysis and math that
18 the Bard engineers did in testing the various IVC filters?

19 A. Well, the mathematics that goes into finite element
20 analysis is identical to the mathematics that goes into doing
21 an analysis on a piece of paper, so yes.

03:58PM

22 Q. And what was the difference between your analysis in math
23 and Bard's analysis in math?

24 A. The assumptions were the difference.

25 Q. And what were the key distinctions in the differences in

03:58PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 the assumptions?

2 A. The key distinction is that I always -- I was always
3 concerned to identify the foreseeable worst-case conditions
4 that the filter would experience whereas when Bard carried out
5 their calculations and their testing, they did not seek
6 worst-case conditions for the exercise.

03:59PM

7 Q. And in your review of their math and their analysis and
8 their finite element analysis tests, did they analyze, in most
9 cases, best-case scenario?

10 A. Yes, essentially best-case scenarios.

03:59PM

11 Q. And all things considered, it's not wrong to do a best case
12 scenario analysis. True?

13 A. No. Correct. It's a good thing to do an analysis of all
14 sorts of scenarios to get a proper and comprehensive assessment
15 of how a device will perform. But that should always be
16 accompanied by analyses that that address the foreseeable
17 worst-case conditions that can arise.

03:59PM

18 Q. And did Bard do the latter?

19 A. No.

20 Q. Were the conditions that you were testing for things that
21 they could not have anticipated?

03:59PM

22 A. They could have anticipated it very easily. It already was
23 known that filters perforate the vena cava, that they tilt, and
24 that they fracture.

25 Q. Well, in particular to the testing that Bard did and the

04:00PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 analysis that Bard did when they were moving from the Recovery
2 Filter to the G2 Filter, they were very aware of the failures
3 that were going on. True?

4 A. Yes. They knew of the Recovery failures that were taking
5 place.

04:00PM

6 Q. And did they test their new design to make sure, hey, we're
7 not going to make things worse or are there ways we could
8 improve on those failures we're experiencing with the Recovery?

9 A. No, they did not.

10 Q. Is that a problem?

04:00PM

11 A. Yes. Very much so.

12 Q. You were asked -- I'm sorry. Did I interrupt?

13 A. No. I just said very much so that was a problem.

14 Q. You were asked some questions about your electropolishing
15 comparisons for fatigue limit analyses and your use of Bard's
16 numbers. Do you recall that?

04:00PM

17 A. I recall it, yes.

18 Q. The question I have for you about that is, why did you use
19 Bard's numbers?

20 A. Because that was the only data available that compared
21 previous versions of the condition of the surface with the new
22 conditions of the -- the new conditions of the surface after
23 electropolishing.

04:01PM

24 Q. Using those numbers, were you able to determine whether the
25 electropolishing would have had an effect on the potential

04:01PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 fracture of these devices?

2 A. It would not have had a meaningful effect because of the
3 very large fatigue strains which the filter was experiencing or
4 could experience in worst-case conditions.

5 Q. Is it fair to say you calculated fatigue strains and then
6 you were able to compare the values that Bard had determined to
7 see whether they were going to be sufficient to overcome that?

04:01PM

8 A. That's correct.

9 Q. And they weren't?

10 A. They weren't.

04:01PM

11 Q. So when you did your analyses, your fatigue failure
12 analyses, what more, if you had done them from scratch as
13 apparently Mr. North contends you did not, what more would you
14 have needed to do in order to determine what differences the
15 electropolishing made with respect to the Eclipse as compared
16 to the G2?

04:02PM

17 A. It's always good to do more testing, but no, there was
18 nothing essential that needed to be done to make that
19 comparison.

20 Q. Mr. North asked you some questions about your testimony as
21 to whether you had created an alternative design, I think it
22 was prototype.

04:02PM

23 Did you ever model a full new filter that Bard could
24 have designed?

25 A. Well, I have thought of them in terms of what is feasible

04:02PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 in a design, but I haven't directly modelled new filters.

2 Q. But you have informed defendants of the elements of design
3 changes that could have been made, correct?

4 A. Yes, I have.

5 Q. And you told them that they could have added caudal
6 anchors?

7 A. Correct.

8 MR. NORTH: Object. Leading.

9 THE COURT: Sustained.

10 BY MR. STOLLER:

11 Q. What design changes have you told these defendants in this
12 litigation that they could have made to the G2 Filter in the
13 Eclipse to make it safer?

14 A. I told them they could have added caudal anchors, that they
15 could have added perforation limiters, that they could have
16 introduced a gentler curve at the mouth of the cap. And I have
17 pointed out that they could have installed a two-tier system
18 much like the Simon Nitinol Filter that was the predicate of
19 the Recovery.

20 Q. Mr. North asked you, well, questioned you about not
21 analyzing the strain in the legs. Do you recall that?

22 A. I recall that, yes.

23 Q. Why did you not?

24 A. Because the strain in the legs, because of their shape and
25 length, is going to be less than, even in the worst-case

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 location of the legs compared to the worst-case location in the
2 arm. And because I am always concerned about worst-case
3 conditions, I focused my attention on what would happen to the
4 arm.

5 I should comment that I did other calculations for 04:04PM
6 legs that were associated with what happens when clots hit
7 them. So I did do some analysis of leg strain but primarily my
8 focus was on arm strain.

9 Q. And that focus on the arm strain was because why?

10 A. Because it's the worst-case location in terms of 04:04PM
11 susceptibility to fatigue failure.

12 Q. Does that mean it's the most likely to fail if failure
13 happens?

14 A. That's correct.

15 Q. And Mr. North asked you some questions about how often or 04:04PM
16 how frequent these things would occur within what time period
17 assuming all these various events that you have assumed the
18 worst-case scenario would happen.

19 How long would it take under some of your calculations
20 for the filter to break? 04:05PM

21 A. Well, in some cases it would take years of breathing. In
22 other cases, it could happen quite quickly after the worst-case
23 conditions have set in. But it always takes time for the
24 worst-case conditions to set in because that involves
25 endothelialization which develops over weeks or months and 04:05PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 perforation, which probably takes months or years.

2 Q. And what are the worst-case conditions?

3 A. The worst-case conditions for the filter are perforated to
4 the extent that it looks just like this. Sorry. Can I put the
5 ELMO on?

04:05PM

6 MR. STOLLER: Your Honor, may we show the jury the
7 ELMO?

8 THE COURT: Yes.

9 MR. STOLLER: Thank you.

10 THE WITNESS: So the worst-case condition is when the
11 filter has perforated through the wall of the vena cava so that
12 the arms at least look like this. They have regained their
13 original shape and the filter is tilted and it has
14 endothelialized so that walls of the vena cava grip the arms
15 firmly, and the expansion and contraction of the vena cava is
16 high because of breathing, which is a possibility in some
17 individuals who would receive filters.

04:05PM

04:06PM

18 BY MR. STOLLER:

19 Q. Does tilting happen in filters?

20 A. Yes.

04:06PM

21 Q. Does perforation happen in filters?

22 A. Yes.

23 Q. Does endothelialization happen in filters?

24 A. Yes.

25 Q. Is that the situation that you tested?

04:06PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 A. I tested it in calculations, yes.

2 Q. And it takes time to get to that condition?

3 A. That's correct.

4 Q. But once you reach that condition it is in a critical state
5 where it may fracture?

04:07PM

6 A. That's correct.

7 Q. And you were not -- were you testing for everyday normal
8 use?

9 A. No. I was testing for worst-case conditions.

10 Q. And those worst-case conditions exist in reality, correct?

04:07PM

11 A. They can occur in reality, yes, and given the number of
12 individuals who have filters, I'm sure they do, in fact, happen
13 in practice.

14 Q. You were asked a number of questions about the effect of
15 the cap changes to the G2X on your opinions and the filter
16 fracture and the fact that you did not take those into account.
17 Why did you not take into account the G2X cap changes?

04:07PM

18 A. Because the change of shape would have no effect on the
19 fatigue strains that would be imposed on the arm. And so the
20 cap was irrelevant to the calculation that I was doing.

04:08PM

21 Q. What's the important part of the cap for your calculation?

22 A. The important part of the cap is where the arm comes out of
23 the cap, and that's the location of the worst-case strains in
24 the arm anyway. And it's also the location of where the strain
25 concentration can be elevated because of interference between

04:08PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 the arm and the cap.

2 Q. Do your calculations mask potential reality?

3 A. Yes.

4 Q. Do Bard's filters fail in the way that you have calculated
5 and determined they might?

04:08PM

6 A. Yes, they do.

7 Q. Have you seen real life failures that match the
8 calculations that you have done?

9 A. I have seen papers which summarize failures of the type
10 that I have described. And, of course, there are litigation
11 cases about patients who have suffered similar failures.

04:08PM

12 Q. Mr. North asked you questions about the degree of tilt in
13 this case and whether that might lead to perforation or other
14 adverse events. In this case, Mrs. Jones had a fracture. You
15 are aware of that, correct?

04:09PM

16 A. Yes, I am. Yes.

17 Q. And you have done a specific analysis of the reason why her
18 filter fractured, correct?

19 A. Correct.

20 Q. But did her filter suffer from some of the complications
21 that you calculated and determined were reasonably likely to
22 happen?

04:09PM

23 A. Yes, it did.

24 Q. And does even what Mr. North characterized as minor tilt
25 increase the stresses and strains on the vulnerable parts of

04:09PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 the filter?

2 A. Yes, it would.

3 Q. Why is that?

4 A. Because the process is proportional. A small amount of
5 tilt would make a small change; a big amount of tilt would make
6 a big change. But if the conditions such as the strain
7 concentration is already severe, a small amount of tilt could
8 be enough to take something which was okay over the critically
9 dangerous condition.

04:10PM

10 Q. Mr. North asked you some questions about whether you had
11 conducted bench testing or animal testing. You are familiar
12 with the reports of their expert, Dr. Briant, in this case, are
13 you not?

04:10PM

14 A. Yes, I am.

15 Q. Did Dr. Briant do any animal testing?

04:10PM

16 A. No.

17 Q. Did Dr. Briant do any bench testing?

18 A. Oh, he did some bench testing to compare with some of his
19 calculations, but they weren't bench tests that would address
20 filter tilt or perforation or fracture by fatigue.

04:10PM

21 Q. And did he do any bench testing to duplicate what Bard had
22 done?

23 A. No.

24 Q. Did he evaluate Bard's testing?

25 A. Not to my knowledge. It's not in the report.

04:11PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 Q. Is his report aimed solely at criticizing your results?

2 A. That appears to be the case, yes.

3 Q. Have you seen whether Dr. Briant has done any analysis of
4 Bard's FEA analyses and said these were correctly done?

5 A. I'm not aware of anything in his report that addresses
6 that. So my answer would be no.

04:11PM

7 Q. Has Dr. Briant done a root cause analysis and offered any
8 ideas about why Bard's filters are suffering the complications
9 they do?

10 A. No, he has not.

04:11PM

11 MR. NORTH: Objection, Your Honor. Outside the scope
12 of cross.

13 THE COURT: Overruled.

14 BY MR. STOLLER:

15 Q. I'm sorry?

04:11PM

16 A. No, he has not.

17 Q. Has he offered any opinions as to how Bard could improve
18 its filters?

19 A. No, he has not.

20 Q. Mr. North has asked you some questions about having done
21 work for the plaintiffs lawyers in this case and other matters
22 and the amounts that were paid to you. Do you recall that?

04:11PM

23 A. I do, yes.

24 Q. Have you charged us the same amounts you charge all of your
25 consulting clients?

04:12PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 A. For other than testimony, yes. The figure is exactly the
2 same.

3 Q. Have you seen the experts from Dr. Fasching -- I'm sorry --
4 have you seen Dr. Fasching and Dr. Briant in those same
5 litigations?

04:12PM

6 A. You mean in the Bard litigation?

7 Q. Yes, sir.

8 A. Yes. They are involved in all the Bard litigation that I'm
9 aware of.

10 MR. NORTH: Your Honor, could we approach, please?

04:12PM

11 THE COURT: Yes. You can stand up Ladies and
12 Gentlemen.

13 (Discussion was had at sidebar out of the hearing of
14 the jury:)

15 THE COURT: After that last objection I started
16 searching my notes. You were the one who brought up Briant.

04:12PM

17 MR. STOLLER: I did bring up Briant on direct.

18 THE COURT: Did you address Briant on cross?

19 MR. NORTH: I did not.

20 THE COURT: I remembered Briant so I overruled it.

04:13PM

21 But it seems to me he didn't talk about Briant.

22 MR. STOLLER: The particular issue here he's
23 questioned the amount of money he's made and his involvement in
24 litigation with them. I think it's fair game to say have you
25 seen the same experts on the other side, same litigation. They

04:13PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 are challenging his credibility.

2 THE COURT: I understand your objection. You don't
3 need to tell me what they are challenging his credibility.

4 What's your response to the objection?

5 MR. STOLLER: My response is they have opened the door
6 by challenging him on these issues as claiming that he has
7 bought and paid for us because he has appeared in a number of
8 litigations for us.

9 THE COURT: I understand that point.

10 MR. NORTH: I had another objection. I think they are
11 crossing the line on the order in the Motion in Limine about
12 the litigation. My questions to him were carefully phrased in
13 terms of in this litigation. And all I said was tens of
14 thousands of dollars in this litigation. And they are now
15 talking about -- he's already slipped in other cases once. And
16 I just want didn't want to make a big deal about objecting to
17 it. I thought it would give it to much prominence. But that
18 last question is inviting him to talk about other lawsuits. I
19 mean, he's been involved in this litigation since before Mr.
20 Stoller was.

21 THE COURT: How do you think you were limited in your
22 questions?

23 MR. NORTH: I said you have charged tens of thousands
24 of dollars in this litigation.

25 THE COURT: By "this litigation" did you think he was

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 thinking the Jones case or the Bard MDL?

2 MR. NORTH: I think he maybe thinking Bard MDL. But
3 it's generic and it's carefully worded not to give the
4 impression of multiple cases.

5 THE COURT: Do you agree, then, that the plaintiff can 04:14PM
6 inquire into -- or bring before the jury the fact that Briant
7 has charged comparable amounts in this litigation?

8 MR. NORTH: Yes. And I am concerned about this
9 witness has already mentioned in terms of other lawsuits, I
10 believe, and I don't think that is -- 04:15PM

11 THE COURT: So where are you going with that?

12 MR. STOLLER: I think Mr. North has not accurately
13 stated his questions on cross-examination. He did ask that
14 question. He also asked a follow-up question about being
15 involved with these lawyers in multiple litigations. 04:15PM

16 THE COURT: And I don't have the testimony.

17 MR. STOLLER: He talked about the hook. He also moved
18 to this litigation and talked about paid, by these lawyers,
19 money in multiple litigations.

20 THE COURT: I don't remember that. 04:15PM

21 MR. STOLLER: I think the transcript -- I don't have
22 the transcript in front of me. What I do have is my notes
23 which said he's opened the door to talking about other
24 engagements by his experts in the same litigation.

25 THE COURT: Is Briant going to testify? 04:15PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 MR. STOLLER: Yes.

2 THE COURT: Why isn't this appropriate for Briant on
3 cross?

4 MR. STOLLER: It is appropriate for Briant on cross.
5 It's also appropriate for a witness who has just been impugned
6 in front of this jury at this time to know now --

04:15PM

7 THE COURT: It seems to me you are suggesting you
8 should be able to put in front of this jury the fact that there
9 are multiple other lawsuits against Bard.

10 MR. STOLLER: No. What I'm saying is to the extent
11 they have examined -- well, let me say I think they have opened
12 the door to multiple other lawsuits with regards to amounts of
13 money he has been paid in other instances.

04:16PM

14 THE COURT: Hold on, Mr. Stoller. Their saying he has
15 been paid a lot of money by you guys doesn't necessarily say
16 anything about multiple other lawsuits against Bard. I don't
17 think that fact has been brought out. You just said, I think,
18 that you think you should be able to bring out multiple other
19 lawsuits against Bard.

04:16PM

20 MR. STOLLER: I do.

04:16PM

21 THE COURT: Why?

22 MR. STOLLER: Because I think they have opened the
23 door.

24 THE COURT: I disagree on that, and I ruled on that in
25 a Motion in Limine. I do think it's fair for you to bring out

04:16PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 the fact that Briant has been paid comparable amounts of money
2 but I think you can do that without bringing out the fact that
3 there are multiple lawsuits against Bard, can't you?

4 MR. STOLLER: I don't think he knows the money, what
5 he knows is Dr. Briant and Dr. Fasching have been in the same
6 litigation against -- not every time but in the Bard.

04:17PM

7 THE COURT: So it sounds like the only way you can do
8 it is to bring out the fact that there are multiple lawsuits
9 against Bard with this witness?

10 MR. STOLLER: He can't talk about money. That's
11 correct.

04:17PM

12 THE COURT: And I have already ruled on a Motion in
13 Limine we shouldn't get into multiple lawsuits.

14 MR. STOLLER: I don't disagree with you, Your Honor.
15 I think their questioning opened up by virtue of -- he's
16 interpreted this litigation as being the Bard litigations. The
17 questions he talked about Cook, he tried not to open the door
18 on theirs and gets into how much the Cook litigation is like
19 this litigation.

04:17PM

20 THE COURT: My problem is that I can't agree with you
21 without going back and looking at the transcript on this. I
22 don't know how to do that with the jury waiting and 15 minutes
23 left. Now, if you want I can quickly search the Livenote to
24 see if I can agree with what you said about other litigations.
25 I don't know if I can find it.

04:17PM

04:18PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 MR. STOLLER: He didn't use the word "other
2 litigations." He asked him this litigation and I believe he
3 said "other matters." I believe it was "other matters."

4 THE COURT: That's what I don't know. But so just so
5 I understand, when I look at the transcript your argument is
6 that you should be able to ask this witness of whether he has
7 faced Briant in other cases like this against Bard?

04:18PM

8 MR. STOLLER: Yes. I think they asked him the
9 questions that he has worked for the lawyers in this case in on
10 other matters.

04:18PM

11 THE COURT: Okay. That's what I will go look for.

12 When Mr. North asked the question he said, and this
13 was right at the beginning of the cross-examination, "You have
14 worked with these lawyers for a number of years, haven't you?"
15 And he said yes. "And they have paid you tens of thousands of
16 dollars."

04:22PM

17 His next question was you have also worked on the Cook
18 litigation with these lawyers, and they had a back and forth
19 about whether it was these lawyers. So he went from a number
20 of years to the Cook litigation. The only time my search found
21 where he mentioned other cases was in response to your question
22 on direct when he said I have worked on the other Bard cases.
23 But the cross-examination was limited to these lawyers for a
24 number of years and the Cook litigation.

04:22PM

25 So in light of that, tell me one more time why you

04:22PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 think you should be able to bring out other cases against Bard
2 in this redirect.

3 MR. STOLLER: I recall three things and one of which I
4 may be wrong. I recall him asking him about aside from the
5 Cook litigation other matters. Secondly, the number of years 04:23PM
6 this doctor is going to interpret as all of them, second. And
7 thirdly, I am fairly certain, I believe, that there was a
8 mention of depositions in other matters as well.

9 THE COURT: The mention of the depositions that I just
10 read was two: One he said you charged the same amount for 04:23PM
11 testifying in a deposition as in trial. True. And then he
12 brought out the fact that he was in effect testifying by
13 deposition videotape in another Cook trial going on right now.
14 I think those were the two references to depositions. I will
15 go search for "matters" to see -- 04:23PM

16 MR. STOLLER: The word matters sticks in my mind.
17 Also I think the years thing is ambiguous. It opened the door
18 to this completely.

19 THE COURT: The word "matters" appears only one time
20 this afternoon and it was in your redirect about the fatigue 04:24PM
21 testing. So in response to your argument, I don't agree that
22 the question about working for years opens the door to bring in
23 the other Bard cases. I just don't think that opens the door
24 on that.

25 MR. STOLLER: Your Honor, the only work he has done in 04:25PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 this case has been last year and this year. That's not years.

2 THE COURT: All the more. He's just limited his
3 answer to that then. He said yes I have been paid tens of
4 thousands of dollars. Now you can go into Briant on the amount
5 he's been paid.

04:25PM

6 MR. STOLLER: This witness doesn't know that.

7 THE COURT: He doesn't. And my view is they haven't
8 opened the door on other Bard cases as to what he's been paid
9 over the number of years. So that's my ruling.

10 MR. STOLLER: Thank you, Your Honor.

04:25PM

11 (In open court.)

12 THE COURT: Thank you for your patience, Ladies and
13 Gentlemen.

14 BY MR. STOLLER:

15 Q. Dr. McMeeking, Mr. North asked you whether the risks in
16 these devices could be reduced to zero. I believe you said
17 that that was unlikely. Could the risks in these devices, and
18 particularly the Eclipse, have been less than they were?

04:25PM

19 A. Yes.

20 Q. How?

04:26PM

21 A. Well, the addition of perforation limiters and caudal
22 anchors would have helped to reduce the risk of some of the
23 failures without making any significant change to the benefits.

24 Q. And you have identified some of those changes that you
25 believe could have been made, correct?

04:26PM

5-16-18-MD 15-2641-Jones v Bard-Jury Trial-Day 2-McMeeking-Redirect

1 A. That's correct.

2 Q. And you testified to them and identified some of them in
3 your reports?

4 A. I did, yes.

5 Q. Has Bard ever asked you to consult with them about how they 04:26PM
6 could fix their filters?

7 A. No.

8 Q. Have they implemented, to your knowledge -- well, did they
9 implement at the time you gave them the suggestions you have
10 made? 04:27PM

11 A. Not to my knowledge.

12 Q. Would those have made for a safer filter?

13 A. Yes.

14 MR. STOLLER: No further questions, Your Honor.

15 THE COURT: Thank you, Dr. McMeeking. 04:27PM

16 Ladies and Gentlemen, we're virtually at the end of
17 the day. We'll break now. We'll plan to start at 9:00.
18 Please remember not to discuss the case. And we'll see you in
19 the morning. Thank you. You can step down.

20 THE COURT: Counsel, for your information, plaintiff 04:29PM
21 has used five hours and 49 minutes. Defendant has used two
22 hours and 35 minutes as of the end of today. We will plan to
23 see you tomorrow morning at 8:30. We've got another hearing
24 starting now.

25 (Proceeding recessed at 4:29 p.m.) 04:29PM

C E R T I F I C A T E

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 16th day of May, 2018.

s/Laurie A. Adams

Laurie A. Adams, RMR, CRR